

# Sunshine Act Meetings

Federal Register

Vol. 53, No. 224

Monday, November 21, 1988

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

## FEDERAL DEPOSIT INSURANCE CORPORATION

### Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 5:20 p.m. on Tuesday, November 15, 1988; the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters relating to: (1) The Corporation's supervisory activities; (2) the possible closing of certain insured banks; and (3) an assistance agreement pursuant to section 13(c) of the Federal Deposit Insurance Act.

In calling the meeting, the Board determined, on motion of Director C.C. Hope, Jr. (Appointive), seconded by Director Robert L. Clarke (Comptroller of the Currency), concurred in by Chairman L. William Seidman, that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(2), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(2), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

The meeting was held in Room 6221 of the FDIC Building located at 550—17th Street, NW., Washington, DC.

Dated: November 16, 1988.

Federal Deposit Insurance Corporation.

M. Jane Williamson,

Assistant Executive Secretary.

[FR Doc. 88-26917 Filed 11-17-88; 11:51 am]

BILLING CODE 6714-01-M

## NATIONAL COUNCIL ON THE HANDICAPPED

### Quarterly Meeting

**SUMMARY:** This notice sets forth the schedule and proposed agenda of a

forthcoming meeting of the National Council on the Handicapped. This notice also describes the functions of the Council. Notice of this meeting is required under section 522 (b) (10) of the "Government in the Sunshine Act" (Pub. L. 94-409).

### DATES:

Nov. 28, 1988, 9:00 a.m. to 5:00 p.m.

Nov. 29, 1988, 9:00 a.m. to 5:30 p.m.

Nov. 30, 1988, 8:30 a.m. to 1:00 p.m.

**LOCATION:** Grand Hyatt Hotel, Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** National Council on the Handicapped, 800 Independence Avenue, SW, Suite 814, Washington, DC 20591, (202) 267-3846, TDD: (202) 267-3232.

The National Council on the Handicapped is an independent Federal agency comprised of 15 members appointed by the President of the United States and confirmed by the Senate. Established by the 95th Congress in Title IV of the Rehabilitation Act of 1973 (as amended by Public Law No. 95-602 in 1978), the Council was initially an advisory board within the Department of Education. In 1984, however, the Council was transformed into an independent agency by the Rehabilitation Act Amendments of 1984 (Public Law No. 98-221).

The Council is charged with reviewing all laws, programs, and policies of the Federal Government affecting disabled individuals and making such recommendations as it deems necessary to the President, the Congress, the Secretary of the Department of Education, the Commissioner of the Rehabilitation Services Administration, and the Director of the National Institute on Disability and Rehabilitation Research (NIDRR).

The meeting of the Council shall be open to the Public. The proposed agenda includes:

Report from the Chairperson and Executive Committee

Forum: Implementing Public Policy In Toward Independence, cosponsored by the District of Columbia Mayor's Committee on Persons with Disabilities.

Committee Meetings

Press Conference in the "Disability Prevention Initiative"

## Discussion of Unfinished and New Business

Records shall be kept of all Council proceedings and shall be available after the meeting for public inspection at the National Council on the Handicapped.

Signed at Washington, DC, on November 10, 1988.

Paul G. Hearne,

Executive Director.

[FR Doc. 88-26978 Filed 11-17-88; 3:39]

BILLING CODE 6820-BS-M

## NATIONAL SCIENCE BOARD

### DATE AND TIME:

December 1, 1988 8:00 a.m. Closed Session

December 2, 1988 8:30 a.m. Closed Session

December 2, 1988 9:00 a.m. Closed Session

**PLACE:** National Science Foundation, 1800 G Street, NW, Room 540, Washington, DC 20550.

**STATUS:** Most of this meeting will be open to the public. Part of this meeting will be closed to the public.

### MATTERS TO BE CONSIDERED ON DECEMBER 1:

#### Committee on Programs and Plans

Closed Session (8:00 a.m. to 1:00 p.m.)

Grants and Contracts. During discussion of certain proposed awards the Committee may be joined by enough other Board members to constitute a quorum.

### MATTERS TO BE CONSIDERED ON DECEMBER 2:

#### National Science Board

Closed Session (8:30 a.m. to 9:00 a.m.)

1. Minutes—October 1988 Meeting
2. NSB and NSF Staff Nominees
3. Grants and Contracts

Open Session (9:00 a.m.—12:00 noon)

4. Grants, Contracts, and Programs
5. Chairman's Report
6. Minutes—October 1988 Meeting
7. Director's Report
8. Draft Report of the NSB Committee on Openness of Scientific Communication
9. Inspector General Provisions
10. Presentation by Dr. Carl Lineberger: "The Laser Revolution in Chemical Physics"
11. Other Business

Thomas Ubois,

Executive Officer.

[FR Doc. 88-26901 Filed 11-17-88 1:50 p.m.]

BILLING CODE 7555-01-M

# Corrections

Federal Register

Vol. 53, No. 224

Monday, November 21, 1988

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents and volumes of the Code of Federal Regulations. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket Nos. CP87-428-001 et al.]

### CNG Transmission Corp. et al.; Natural Gas Certificate Filings

#### Correction

In notice document 88-26311 beginning on page 45960 in the issue of Tuesday, November 15, 1988, make the following correction:

On page 45962, in the first column, after 8. Amoco Production Company, the "Docket No." should read "CI88-94-002".

BILLING CODE 1505-01-D

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 61

[FRL-3449-9]

### National Emission Standards for Hazardous Air Pollutants Subparts and Test Methods; Technical Corrections

#### Correction

In rule document 88-21393 beginning on page 36972 in the issue of Friday, September 23, 1988, make the following corrections:

#### § 61.70 [Corrected]

1. On page 36972, in the second column, in amendatory instruction 6, in the fifth line, "M" should read "P<sub>GI</sub>".

#### Appendix B— [Corrected]

2. On page 36973, in the first column,

in the equation following amendatory instruction 21, between "/" and "10<sup>3</sup>", insert "[".

BILLING CODE 1505-01-D

## ENVIRONMENTAL PROTECTION AGENCY

[OPP-180791; FRL-3467-5]

### Maryland Department of Agriculture, Receipt of Applications for Emergency Exemptions To Use (±)-2-[4,5-Dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-ethyl-3-pyridinecarboxylic acid; Solicitation of Public Comment

#### Correction

In notice document 88-24590 beginning on page 43269 in the issue of Wednesday, October 26, 1988, make the following corrections:

1. On page 43269, in the second column, under **SUBJECT**, in the fifth line, the formula should read "(±)-2-[4,5-dihydro-".

2. On the same page, in the third column, under **SUPPLEMENTARY INFORMATION**, in the second paragraph, in the fourth line, the formula should read "(±)-2-[4,5-".

BILLING CODE 1505-01-D

## FEDERAL RESERVE SYSTEM

### 12 CFR Part 229

[Regulation CC; Docket No. R-0648]

### Availability of Funds and Collection of Checks

#### Correction

In proposed rule document 88-25039 beginning on page 44335 in the issue of Wednesday, November 2, 1988, make the following correction:

#### § 229.36 [Corrected]

On page 44341, in the third column, in § 229.36(f), the sixth line should read "(b)(5)(i) through (iii) of this section".

BILLING CODE 1505-01-D

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 510

[Docket No. 84N-0036]

### Proposed Removal of Regulation Regarding Sulfonamide-Containing Drugs for Use in Food-Producing Animals

#### Correction

In proposed rule document 88-21057 beginning on page 35833 in the issue of Thursday, September 15, 1988, make the following correction:

On page 35833, in the first column, the CFR Part heading should read as it appears above.

BILLING CODE 1505-01-D

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

[AZ-020-09-4212-12; A 20346-0]

### Realty Action, Exchange of Public Lands, Navajo and Apache Counties, AZ

#### Correction

In notice document 88-24302 appearing on page 41247 in the issue of Thursday, October 20, 1988, make the following correction:

In the third column, the 33rd line should read "Sec. 4, lot 1, SE¼NE¼, E½SE¼".

BILLING CODE 1505-01-D

## DEPARTMENT OF THE INTERIOR

### Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 701, 780, 784, 815, 816, and 817

### Surface Coal Mining and Reclamation Operations; Permanent Regulatory Program; Reclamation and Operation Plan; Performance Standards; Roads

#### Correction

In rule document 88-25688 beginning

on page 45190 in the issue of Tuesday, November 8, 1988, make the following corrections:

1. On page 45195, in the second column, in the second complete paragraph, in the second line, "technology" should read "terminology".

2. On page 45197, in the second column, in the second complete paragraph, in the ninth line, after "performance" insert "standards".

3. On page 45201, in the second column, in the second complete paragraph, in the 17th line, "has" should read "had".

BILLING CODE 1505-01-D

#### DEPARTMENT OF TRANSPORTATION

##### Coast Guard

##### 33 CFR Part 158

[CGD 88-002]

RIN 2115-AC89

##### Regulations Implementing the Pollution Prevention Requirements of Annex V of MARPOL 73/78

##### Correction

In proposed rule document 88-24616 beginning on page 43622 in the issue of Thursday, October 27, 1988, make the following corrections:

##### § 158.120 [Corrected]

On page 43645, in the second column, in paragraph (4), in § 158.120, the definition for "Recreational boating facility" should read:

"Recreational boating facility" means a port that can provide wharfage or other services to 10 or more recreational vessels. It includes but is not limited to marinas, boatyards, and yacht clubs. It does not include a place or facility containing only an unattended launching ramp.

BILLING CODE 1505-01

#### DEPARTMENT OF TRANSPORTATION

##### Maritime Administration

##### 46 CFR Part 390

[Docket No. R-120]

##### Capital Construction Fund

##### Correction

In proposed rule document 88-25110 beginning on page 43907 in the issue of Monday, October 31, 1988, make the following correction:

On page 43908, in the first column, in the third complete paragraph, the third line should read "not be deductible as an expense from the".

BILLING CODE 1505-01-D

# Discussion

The first question that arises in the mind of the reader is whether the authors have provided sufficient evidence to support their conclusions. The answer is yes, for they have presented a series of carefully controlled experiments which have shown that the proposed mechanism is indeed operative. The second question is whether the authors have provided sufficient evidence to support their conclusions. The answer is yes, for they have presented a series of carefully controlled experiments which have shown that the proposed mechanism is indeed operative.

## Comments by Other Authors

The following comments are from other authors who have read the paper and have expressed their views on the subject.

Dr. [Name] has expressed his agreement with the authors' conclusions and has stated that the evidence presented is convincing.

Dr. [Name] has expressed his disagreement with the authors' conclusions and has stated that the evidence presented is not convincing.

Dr. [Name] has expressed his agreement with the authors' conclusions and has stated that the evidence presented is convincing.

## References

1. [Reference 1]

2. [Reference 2]

3. [Reference 3]

4. [Reference 4]

5. [Reference 5]

6. [Reference 6]

7. [Reference 7]

8. [Reference 8]

The second question that arises in the mind of the reader is whether the authors have provided sufficient evidence to support their conclusions. The answer is yes, for they have presented a series of carefully controlled experiments which have shown that the proposed mechanism is indeed operative.

The third question that arises in the mind of the reader is whether the authors have provided sufficient evidence to support their conclusions. The answer is yes, for they have presented a series of carefully controlled experiments which have shown that the proposed mechanism is indeed operative.

## Department of Translocation

The following comments are from other authors who have read the paper and have expressed their views on the subject.

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## Medical and Surgical Cases

1. [Case 1]

2. [Case 2]

3. [Case 3]

4. [Case 4]

5. [Case 5]

6. [Case 6]

7. [Case 7]

8. [Case 8]

The fourth question that arises in the mind of the reader is whether the authors have provided sufficient evidence to support their conclusions. The answer is yes, for they have presented a series of carefully controlled experiments which have shown that the proposed mechanism is indeed operative.

The fifth question that arises in the mind of the reader is whether the authors have provided sufficient evidence to support their conclusions. The answer is yes, for they have presented a series of carefully controlled experiments which have shown that the proposed mechanism is indeed operative.

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# Test Report

Monday  
November 21, 1988

## Part II

## Department of Transportation

### Office of the Secretary

#### 49 CFR Part 40

#### Procedures for Transportation Workplace Drug Testing Programs; Interim Final Rule

**DEPARTMENT OF TRANSPORTATION****Office of the Secretary****49 CFR Part 40**

[Docket No. 45928 Notice No. 88-17]

RIN 2105-AB42

**Procedures for Transportation Workplace Drug Testing Programs****AGENCY:** Office of the Secretary, DOT.**ACTION:** Interim final rule.

**SUMMARY:** The Department of Transportation is adopting a modification of the Department of Health and Human Services' "Mandatory Guidelines for Federal Workplace Programs." The purpose of the modification is to adapt the procedures and safeguards developed by the Department of Health and Human Services more closely to the circumstances of drug testing programs in industries regulated by the Department of Transportation. Antidrug program rules published by the Department's operating administrations will require employers to conduct drug testing according to these Procedures.

**DATES:** This rule is effective December 21, 1988. Comments should be received by January 23, 1989. Late-filed comments will be considered to the extent practicable.

**ADDRESS:** Comments should be sent to Docket Clerk, Docket 45928, Department of Transportation (C-55), 400 7th Street SW., Room 4107, Washington, DC., 20590. In order to expedite handling of comments, commenters are requested to refer to the docket number for this rule and to provide an original and four copies of their comments. Commenters wishing to have their comments acknowledged should include a stamped, self-addressed postcard with their comments. The docket clerk will time and date stamp the card and mail it back to the commenter.

**FOR FURTHER INFORMATION CONTACT:** Robert C. Ashby, Deputy Assistant General Counsel for Regulation and Enforcement, Department of Transportation, 400 7th Street, SW., Room 10424, Washington DC, 20590. Mr. Ashby's phone number is 202-366-9306.

**SUPPLEMENTARY INFORMATION:** The Department of Transportation (DOT) believes that a drug-free transportation workplace is essential to transportation safety. For this reason, the Department's operating administrations (the Federal Aviation Administration, Federal Highway Administration, Federal Railroad Administration, United States Coast Guard, Urban Mass

Transportation Administration, and Research and Special Programs Administration) are issuing regulations requiring antidrug programs in the aviation, motor carrier, railroad, maritime, mass transit, and pipeline industries, respectively.

The proposed regulations for these operating administration rules proposed that employers conduct drug testing according to the "Mandatory Guidelines for Federal Workplace Drug Testing Programs" of the Department of Health and Human Services (DHHS). The "HHS Guidelines," as this document is known, were published in the *Federal Register* on April 11, 1988 (53 FR 11970). They were based on a notice of proposed rulemaking (NPRM) published August 14, 1987 by DHHS, and on comments to that NPRM.

The HHS Guidelines include procedures for collecting urine samples for drug testing, procedures for transmitting the samples to testing laboratories, testing procedures, procedures for evaluating test results, quality control measures applicable to the laboratories, recordkeeping and reporting requirements, and standards and procedures for HHS certification of drug testing laboratories. The intent of the Guidelines is to safeguard the accuracy of test results and the privacy of individuals who are tested.

The Department believes that the basic requirements of the Guidelines must remain a vital component of DOT drug testing regulations. However, the Department is aware that the Guidelines, as written by HHS to apply to testing by Federal agencies, do not fit perfectly the circumstances of employers regulated by DOT. There are many references to legal authorities and other matters which are peculiar to Federal agencies (e.g., references to the Privacy Act and to Executive Order 12564). Terminology referring to Federal "agencies" rather than to "employers" may be confusing in the DOT regulated industry context. One purpose of this rule is to make necessary editorial changes to adapt the content of the HHS Guidelines to the context of industries regulated by DOT.

In addition, DHSS drafted the Guidelines to apply to the physical and organizational circumstances of Federal agencies. Obviously, the circumstances of industries regulated by DOT are very different from those of Federal agencies. For this reason, the Department is modifying some provisions of the HHS Guidelines to work better in the implementation of drug testing programs by DOT regulated industries. These revisions are intended to leave intact

the safeguards for accuracy and privacy in drug testing established by the HHS Guidelines while ensuring that parties regulated by DOT can practically implement the requirements.

We would call particularly to the attention of commenters the following revisions. This is not an exhaustive list of all modifications to the HHS Guidelines published in this document. The Department seeks comments on all aspects of this interim final rule.

In § 40.2, definitions of "employer" and "employee" have been added. The former definition includes consortia, but points out that individual members of a consortium are not relieved of their responsibilities under the rule by virtue of participation in the consortium. As provided in the operating administration drug rules, the testing rate of 50 percent can relate to the entire employee population covered by a consortium; the definition does not mean that 50 percent of the work force of each consortium member must be tested in a year.

Under the HHS Guidelines, a Federal agency may test a urine sample *only* for certain specified drugs. The Department's Procedures echo this requirement. Under § 40.21(c), an employer may test the sample obtained under a DOT drug rule only for the drugs required or specifically authorized to be tested under the DOT drug rule. That is, an employer must test the sample for the five major drugs listed in each DOT drug regulation. If the DOT agency involved authorizes testing for Drug X under § 40.21(b), the employer may also test the sample for that drug. If the employer wants to test, in addition, for Drug Y, the employer must obtain a second sample from the employee. The obtaining of this second sample is not under the authority of the DOT regulation. The employer must base its request for the second sample on whatever other legal authority is available, since the employer cannot rely on the DOT regulation as the basis for the request.

As alluded to above, an employer may submit to the DOT agency involved a protocol for testing another controlled substance (see § 40.21(b)). DOT agencies have discretion whether or not to entertain such requests; if a DOT agency approves such a request, then the employer can test for the drug as part of its DOT-mandated program.

The HHS Guidelines require Federal agencies to keep a permanent log book at the collection site. This is a requirement that is likely to be difficult for many employers to meet, particularly where there are scattered or remote locations at which testing must take place. Consequently, the DOT

Procedures will not require a permanent log book. Instead, employers would use a custody and control form (described at § 40.21-1(b)(4)), a copy of which would be retained for permanent record purposes. For the sake of flexibility, an employer could use a different but equivalent form, or a permanent log book, with the approval of the DOT agency involved.

The DOT procedures also seek to add flexibility to the choice and use of collection sites, in view of the variety of circumstances in which employers have to conduct tests (especially post-accident and reasonable cause tests). Collection sites are defined to include any suitable facility (e.g., a medical facility or mobile unit could qualify); a facility without all the security safeguards contemplated for collection sites could be used if samples are under the direct control of collection site personnel; and other water sources are permissible in the facility if the other sources are secured or monitored to ensure that they could not be used to dilute a specimen (see §§ 40.22(a); 40.22(b)(3); 40.22(f)(1)).

Based on the experience DOT has gained with its drug testing program for its own employees, the DOT procedures spell out the grounds on which an employee would be directed to give a sample while being observed (§ 40.22(e)(2)). These circumstances, which are the exclusive circumstances under which observation could be ordered, include a discrepancy in the temperature of the sample; a record of the employee having previously given a sample which had a too-low specific gravity or concentration of creatinine; or observation by the collection site person of conduct clearly and unequivocally indicating an attempt to tamper with a sample. In the latter case, the collection site person would have to get authorization from a higher-level supervisor before ordering the providing of a sample under observation (§ 40.22(f)(23)). The Department seeks comment on whether there are circumstances in which obtaining this authorization would be too difficult or would occasion too great a delay, such that this requirement should be modified or eliminated in such circumstances.

An additional circumstance in which a test can be observed is when that test is part of a rehabilitation program or post-positive testing program. The rationale for this provision is that, given recidivism rates among users of some drugs, and the concern that employees would have to avoid a second positive test, employees may have a greater incentive to "cheat" than in other

circumstances. The Department seeks comment on this provision and its rationale. Should there be limitations on the authority of employers to conduct observed tests in these situations? For example, should the MRO or other appropriate official have to make a determination that a particular employee is likely to warrant observation during a particular test or series of tests? Should there be a temporal limitation on the period during which tests could be observed (e.g., the first two or three tests, the first or second year of post-positive testing)?

One of the purposes of the Procedures is to ensure that a proper chain of custody is maintained. A number of provisions of the Procedures, particularly in § 40.22, deal with this subject. One such provision (§ 40.22(j)(2)) concerns transfer of the specimen from the collection site person to the laboratory.

It is likely, in some circumstances, that the collection site person will transport or mail the sample directly to the laboratory. For example, the collection site person may put the sample in a mailer and turn it over to a mail room employee, who then sends it to the laboratory. However, the chain of custody form will be sealed in the mailer by the collection site person. This could leave a gap in the chain of custody. The Department seeks comment on whether this would be a significant problem and, if so, how to correct it.

Section 40.24(g)(5) requires a laboratory manager or other employee to sign urine custody and control forms. The Department seeks comment on whether this requirement is needed and whether there are other approaches that would be less burdensome.

The HHS Guidelines do not permit laboratories to subcontract any of their drug testing work. In the interest of flexibility of contracting arrangements for employers, the DOT procedures would permit subcontracting under carefully controlled conditions. These conditions include complete processing of and responsibility for a sample by the subcontract laboratory, which must also be HHS-certified (§ 40.24(j)).

The HHS Guidelines require Federal agencies to inspect laboratories before a testing contract is awarded. Believing that such a requirement would be too burdensome for employers, particularly small employers, the DOT procedures eliminate this requirement. However, DOT, DHSS, or any employer may inspect a laboratory at any time (§ 40.24(1)).

Similarly, the HHS Guidelines require Federal agencies contracting with a

particular laboratory to periodically send "blind samples" to the laboratory to test the laboratory's accuracy. Doing so is reasonable for Federal agencies, but it could be very burdensome and costly for small employers. Consequently, the DOT Procedures provide that only large employers (i.e., those with 2,000 or more employees subject to drug testing under the applicable operating administration drug rule) need to follow this practice (§ 40.2(d)(2)(ii)). This relief for small entities is based, in part, on the assumption that most, if not all, HHS-certified laboratories will have contracts with one or more Federal agencies or other large entities, and will therefore be subject to some blind sample testing.

The Department seeks comment on whether this assumption is likely to be correct. If not, what should the Department's response be? The language of the rule would require employers to submit blind samples if the laboratory they work with does not have contracts with entities who would do blind sample testing. Is this reasonable, or would another approach be better? Also, is the 2,000 covered employee cutoff a reasonable one? Should a lower cutoff (e.g., 1,000 covered employees) be used, in order to make it less likely that laboratories would be subject to blind testing from at least some DOT regulated employers? This would also afford employees of more employers the assurance of properly-run drug testing programs which blind sampling provides. Alternatively, should a higher cutoff be used? Another approach that could be taken would be to base the cutoff on the number of specimens submitted by the employer in a year (e.g., 1,000 specimens rather than 2,000 employees, which might include some employers with high numbers of reasonable cause and post-accident tests who might otherwise not have to conduct blind testing.) The Department seeks comment on this approach as well.

#### Regulatory Process Matters

This is not a major rule under Executive Order 12291. It is a significant rule under the Department's Regulatory Policies and Procedures, since it affects several operating administrations and their regulated industries. A regulatory evaluation has not been prepared, since the costs of conducting drug testing conforming with these Procedures have been analyzed in the regulatory evaluations or regulatory impact analyses for the operating administration drug-free transportation workplace program rules.

This rule will affect small entities in all the industries covered by DOT operating administration drug rules. The basic small entity impacts of each rule have been considered as part of the operating administrations' rulemakings. The Department has taken steps, as described in "Supplementary Information," to reduce small entity impacts in such areas as inspections, submission of blind samples, and permanent log books. Consequently, the Department certifies that 49 CFR Part 40 will not have a significant economic impact on a substantial number of small entities.

The Department has considered the Federalism implications of this rule under Executive Order 12612. The Department has determined that this rule does not have sufficient Federalism implications to warrant the preparation of a Federalism assessment. Federalism implications of individual operating administrations' drug rules are discussed in those rulemaking documents.

The reporting and recordkeeping requirements referenced in this regulation have been submitted for Paperwork Reduction Act approval to the Office of Management and Budget by the respective DOT operating administrations in connection with their own drug rules. This is because it is the operating administration rules, rather than this rule, that actually imposes the requirements on regulated parties. However, the Office of the Secretary is seeking OMB approval under the Paperwork Reduction Act for the form described in § 40.21-1(a). A Federal Register notice will be published when Paperwork Act approval is obtained.

This rule has been published without prior opportunity for notice and public comment. The Department finds that it would be impracticable, unnecessary, and contrary to the public interest to seek prior public comment for this rule. This finding is made on the basis of the overriding public interest in ensuring a drug-free transportation workplace, in order to ensure transportation safety and as a step toward controlling the nationwide problem of drug abuse. (There have been previous opportunities for public notice and comment on this subject, obtained by DHSS on the HHS Guidelines, which served as the basis for this rule, and on the operating administration drug rules, which proposed use of the HHS Guidelines.) It is necessary to publish final rules on this subject at this time, so that all parties affected by the operating administration drug rules will know what is expected of them with respect to testing procedures

as they develop their drug-free workplace programs.

The Department will review comments received on this rule and publish a notice responding to the comments. The Department will also make any appropriate changes to the rule at that time. The operating administrations have received some comments on the HHS Guidelines in the course of their drug rulemakings. These comments will be made a part of the docket for this rulemaking and the Department will respond to them along with the other comments we receive. (Many of the changes in the HHS Guidelines made in this rule appear to be responsive to these comments.)

#### List of Subjects in 49 CFR Part 40

Controlled substances,  
Transportation.

Issued this 14th day of November 1988, at Washington, DC.

Jim Burnley,

Secretary of Transportation.

49 CFR Subtitle A is amended by adding Part 40 to read as follows:

### PART 40—PROCEDURES FOR TRANSPORTATION WORKPLACE DRUG TESTING PROGRAMS

#### Subpart A—General

Sec.

40.1 Applicability.

40.2 Definitions.

#### Subpart B—Scientific and Technical Requirements

40.21 The drugs.

40.23 Preparation for testing.

40.25 Specimen collection procedures.

40.27 Laboratory personnel.

40.29 Laboratory analysis procedures.

40.31 Quality assurance and quality control.

40.33 Reporting and review of results.

40.35 Protection of employee records.

40.37 Individual access to test and laboratory certification results.

#### Subpart C—Certification of Laboratories Engaged in Urine Drug Testing

40.41 Use of DHHS-certified laboratories.

Appendix A to Part 40—DHHS Certification Standards

Appendix B to Part 40—Urine Custody and Control Form

Authority: 49 U.S.C. 102, 301.

#### Subpart A—General

##### § 40.1 Applicability.

This part applies to transportation employers (including self-employed individuals) conducting drug urine testing programs pursuant to regulations issued by agencies of the Department of Transportation and to such transportation employers' officers,

employees, agents and contractors, to the extent and in the manner provided in DOT agency regulations.

##### § 40.2 Definitions.

For purposes of this part the following definitions apply:

*Aliquot.* A portion of a specimen used for testing.

*Chain of custody.* Procedures to account for the integrity of each urine specimen by tracking its handling and storage from point of specimen collection to final disposition of the specimen. These procedures shall require that an approved chain of custody form be used from time of collection to receipt by the laboratory and that upon receipt by the laboratory an appropriate laboratory chain of custody form(s) account for the sample or sample aliquots within the laboratory. Chain of custody forms shall, at a minimum, include an entry documenting date and purpose each time a specimen or aliquot is handled or transferred and identifying every individual in the chain of custody. Two forms of chain of custody documents are utilized under this part. An external chain of custody form or "urine custody and control form" (described in § 40.23) is used to document chain of custody to the laboratory. An internal chain of custody form is utilized to document handling and transfer of the original sample container and aliquots within the laboratory.

*Collection site.* A place designated by the employer where individuals present themselves for the purpose of providing a specimen of their urine to be analyzed for the presence of drugs.

*Collection site person.* A person who instructs and assists individuals at a collection site and who receives and makes an initial examination of the urine specimen provided by those individuals. A collection site person shall have successfully completed training to carry out this function or shall be a licensed medical professional or technician who is provided instructions for collection under this part and certifies completion as required herein. In any case where: (a) A collection is observed or (b) collection is monitored by non-medical personnel, the collection site person must be a person of the same gender as the donor.

*Confirmatory test.* A second analytical procedure to identify the presence of a specific drug or metabolite which is independent of the initial test and which uses a different technique and chemical principle from that of the initial test in order to ensure reliability and accuracy. (At this time gas

chromatography/mass spectrometry (GC/MS) is the only authorized confirmation method for cocaine, marijuana, opiates, amphetamines, and phencyclidine.)

**DHHS.** The Department of Health and Human Services or any designee of the Secretary, Department of Health and Human Services.

**DOT agency.** An agency of the United States Department of Transportation administering regulations requiring compliance with this part, including the United States Coast Guard, the Federal Aviation Administration, the Federal Railroad Administration, the Federal Highway Administration, the Urban Mass Transportation Administration, and the Research and Special Programs Administration.

**Employee.** An individual designated in a DOT agency regulation as subject to drug urine testing and the donor of a specimen under this part. As used in this part "employee" includes a final applicant for employment. "Employee" and "individual" or "individual to be tested" have the same meaning for purposes of this part.

**Employer.** An entity employing one or more employees that is subject to DOT agency regulations requiring compliance with this part. As used in this part, "employer" is inclusive of a industry consortium or joint enterprise comprised of two or more employing entities, but no single employing entity is relieved of its responsibility for compliance with this part by virtue of participation in such a consortium or joint enterprise.

**Initial test (also known as screening test).** An immunoassay screen to eliminate "negative" urine specimens from further consideration.

**Medical Review Officer.** A licensed physician responsible for receiving laboratory results generated by an employer's drug testing program who has knowledge of substance abuse disorders and has appropriate medical training to interpret and evaluate an individual's positive test result together with his or her medical history and any other relevant biomedical information.

**Permanent Record Book.** A permanently bound book in which identifying data on each specimen collected at a collection site are permanently recorded in the sequence of collection. May be used in conjunction with a modified urine custody and control form to document collection.

**Reason to believe.** Reason to believe that a particular individual may alter or substitute the urine specimen.

**Secretary.** The Secretary of Transportation or the Secretary's designee may be a contractor or other

recognized organization which acts on behalf of the Secretary in implementing this part.

## Subpart B—Scientific and Technical Requirements

### § 40.21 The drugs.

(a) DOT agency drug testing programs require that employers test for marijuana, cocaine, opiates, amphetamines and phencyclidine.

(b) An employer may include in its testing protocols other controlled substances or alcohol only pursuant to a DOT agency approval, if testing for those substances is authorized under agency regulations and if the Department of Health and Human Services has established an approved testing protocol and positive threshold for each such substance.

(c) Urine specimens collected under DOT agency regulations requiring compliance with this part may only be used to test for controlled substances designated or approved for testing as described in this section and shall not be used to conduct any other analysis or test unless otherwise specifically authorized by DOT agency regulations.

(d) This section does not prohibit procedures reasonably incident to analysis of the specimen for controlled substances (e.g., determination of pH or tests for specific gravity, creatinine concentration, or presence of adulterants).

### § 40.23 Preparation for testing

The employer and certified laboratory shall develop and maintain a clear and well-documented procedure for collection, shipment, and accessioning of urine specimens under this part. Such a procedure shall include, at a minimum, the following:

(a) Utilization of a standard urine custody and control form (carbonless manifold). The form shall be a multiple-part, carbonless record form with an original (part 1) that shall accompany the specimen to the laboratory. Copies shall be provided for the Medical Review Officer (part 2, to go directly to the MRO), the employee (part 3), the collection site (part 4) (if distinct from the employer), and the employer representative (part 5). The form should be a permanent record on which identifying data on the employee and on the specimen collection and transfer process is retained. The form shall be constructed to display, at a minimum, the following elements, which shall appear on its respective parts as indicated:

(1) The following information shall appear on all parts of the form:

(i) A preprinted specimen identification number, which shall be unique to the particular collection.

(ii) The employee's Social Security or employee identification number, which shall be entered by the employee.

(iii) Specification of the type of test conducted (pre-employment, random, etc.), which shall be entered by the employer representative or collector (acting for the employer).

(iv) A block providing that "Collector must note temperature of specimen has been read and record here if not within the range of 32.5—37.7C/90.5—99.8F;" with an area for the required notation.

(v) A chain-of-custody block providing areas to enter the following information for each transfer of possession: purpose of change; released by (signature/print name); received by (signature/print name); date. The words "Provide specimen for testing" and "DONOR" shall be preprinted in the initial spaces.

(vi) Information to be completed by the collection site person, identifying that person and providing the date of collection, the collection site and the telephone number (if any) of the collection site; a space for remarks at which unusual circumstances may be described; and a certification statement as set forth below and a signature block with date which shall be completed by the collection site person:

I certify that the specimen identified on this form is the specimen presented to me by the employee providing the certification below, that I have verified that it bears the same identification number as that set forth above, and that it has been collected, labelled and sealed as required by the instructions provided.

(vii) A block to be completed by the laboratory after analysis of the specimen, providing a space for entry of the laboratory accession number and a certification to read as follows, together with spaces to enter the printed name and signature of the certifying laboratory official and date:

I certify that the specimen identified by this accession number is the same specimen that bears the identification number set forth above, that the specimen has been examined upon receipt, handled and analyzed in accordance with applicable Federal requirements, and that the results attached are for that specimen.

(2) Information to be provided by the employee, which shall appear on parts 2 through 5 of the form only: Employee name (printed); duty location; job title; date of birth; and a certification statement as set forth below, together with a signature block with date which shall be completed by the employee:

I certify that the urine specimen identified on this form is my own; that it is fresh and has not been adulterated in any manner; and that the identification information provided on this form and on the collection bottle is correct. I consent to the submission of this specimen to the certified laboratory designated by my employer, to the analysis of the specimen for controlled substances as provided by Federal requirements, and to the release of test results from that analysis to the Medical Review Officer designated by my employer.

(3) A block to be completed by the employee, which shall appear only on parts 2 and 3 of the form, containing a statement as follows: "If you wish to have prescription or over-the-counter medications you may have taken or been administered within the past 30 days considered as your test results are reviewed, you may list them here:" followed by an adequate writing area to list such substances.

A form meeting the requirements of this paragraph is displayed at Appendix B to this part. The urine custody and control form may include such additional information as may be required for billing or other legitimate purposes necessary to the collection, provided that personal identifying information (other than the employee identification number) may not be provided to the laboratory and employee medical information may appear only on the copies provided to the employee and to the Medical Review Officer. In lieu of a form meeting the above-described criteria, an employer may choose to use a multiple-sample chain of custody form together with a permanent record book maintained at the site of collection to document collection and transfer of specimens under this part, so long as the data elements set forth above are documented, personal identifying information is not disclosed to the laboratory, and the record system is designed in such a manner as to maintain the confidentiality of medical information.

(b) Use of a tamperproof sealing system designed in a manner such that the specimen bottle top can be sealed against undetected opening, the bottle can be identified with a unique identifying number identical to that appearing on the urine custody and control form, and space has been provided to initial the bottle affirming its identity. For purposes of clarity, this part assumes use of a system made up of one or more pre-printed labels and seals (or a unitary label/seal), but use of other, equally effective technologies is authorized.

(c) Use of a shipping container in which one or more specimens and

associated paperwork may be transferred and which can be sealed and initialed to prevent undetected tampering.

(d) Written procedures, instructions and training shall be provided as follows:

(1) Employer collection procedures and training shall clearly emphasize that the collection site person is responsible for maintaining the integrity of the specimen collection and transfer process, carefully ensuring the modesty and privacy of the employee, and is to avoid any conduct or remarks that might be construed as accusatorial or otherwise offensive or inappropriate.

(2) A non-medical collection site person shall receive training in compliance with this part and shall demonstrate proficiency in the application of this part prior to serving as a collection site person. A medical professional, technologist or technician licensed or otherwise approved to practice in the jurisdiction in which collection occurs may serve as a collection site person if that person is provided instructions described in this part and performs collections in accordance with those instructions.

(3) Collection site persons shall be provided with detailed, clearly illustrated written instructions on the collection of specimens in compliance with this part. Employer representatives and employees subject to testing shall also be provided standard written instructions setting forth their responsibilities.

#### § 40.25 Specimen collection procedures.

(a) *Designation of collection site.* (1) Each employer drug testing program shall have one or more designated collection sites which have all necessary personnel, materials, equipment, facilities, and supervision to provide for the collection, security, temporary storage, and shipping or transportation of urine specimens to a certified drug testing laboratory. An independent medical facility may also be utilized as a collection site provided the other applicable requirements of this part are met.

(2) A designated collection site may be any suitable location where a specimen can be collected under conditions set forth in this part, including a properly equipped mobile facility. A designated collection site shall be a location having an enclosure within which private urination can occur, a toilet for completion of urination (unless a single-use collector is used with sufficient capacity to contain the void), and a suitable clean surface for writing. The site must also have a

source of water for washing hands, which, if practicable, should be external to the enclosure where urination occurs.

(b) *Security.* The purpose of this paragraph is to prevent unauthorized access which could compromise the integrity of the collection process or the specimen.

(1) Procedures shall provide for the designated collection site to be secure. If a collection site facility is dedicated solely to urine collection, it shall be secure at all times. If a facility cannot be dedicated solely to drug testing, the portion of the facility used for testing shall be secured during drug testing.

(2) A facility normally used for other purposes, such as a public rest room or hospital examining room, may be secured by visual inspection to ensure other persons are not present and undetected access (e.g., through a rear door not in the view of the collection site person) is not possible. Security during collection may be maintained by effective restriction of access to collection materials and specimens. In the case of a public rest room, the facility must be posted against access during the entire collection procedure to avoid embarrassment to the employee or distraction of the collection site person.

(3) If it is impractical to maintain continuous physical security of a collection site from the time the specimen is presented until the sealed mailer is transferred for shipment, the following minimum procedures shall apply: The specimen shall remain under the direct control of the collection site person from delivery to its being sealed in the mailer. The mailer shall be immediately mailed, maintained in secure storage, or remain until mailed under the personal control of the collection site person.

(c) *Chain of custody.* The chain of custody block of the urine custody and control form shall be properly executed by authorized collection site personnel upon receipt of specimens. Handling and transportation of urine specimens from one authorized individual or place to another shall always be accomplished through chain of custody procedures. Every effort shall be made to minimize the number of persons handling specimens.

(d) *Access to authorized personnel only.* No unauthorized personnel shall be permitted in any part of the designated collection site when urine specimens are collected or stored. Only the collection site person may handle specimens prior to their securement in the mailing container or monitor or observe specimen collection (under the

conditions specified in this part). In order to promote security of specimens, avoid distraction of the collection site person and ensure against any confusion in the identification of specimens, a collection site person shall conduct only one collection procedure at any given time. For this purpose, a collection procedure is complete when the urine bottle has been sealed and initialed, the urine custody and control form has been executed, and the employee has departed the site.

(e) *Privacy.* (1) Procedures for collecting urine specimens shall allow individual privacy unless there is reason to believe that a particular individual may alter or substitute the specimen to be provided, as further described in this paragraph.

(2) For purposes of this part, the following circumstances are the exclusive grounds constituting a reason to believe that the individual may alter or substitute the specimen:

(i) The employee has presented a urine specimen that falls outside the normal temperature range, and the employee declines to provide a measurement of oral body temperature by sterile thermometer, as provided in paragraph (f)(23) of this part, or the oral temperature does not equal or exceed that of the specimen.

(ii) The last urine specimen provided by the employee (i.e., on a previous occasion) was determined by the laboratory to have a specific gravity of less than 1.003 and a creatinine concentration below .2 g/L.

(iii) The collection site person observes conduct clearly and unequivocally indicating an attempt to substitute or adulterate the sample (e.g., substitute urine in plain view, blue dye in specimen presented, etc.).

(iv) The employee has previously been determined to have used a controlled substance without medical authorization and the particular test is being conducted as a part of a rehabilitation program, on return to service after any required rehabilitation, or under a DOT agency regulation providing for follow-up testing after return to service.

(f) *Integrity and identity of specimen.* Employers shall take precautions to ensure that a urine specimen not be adulterated or diluted during the collection procedure and that information on the urine bottle and on the urine custody and control form can identify the individual from whom the specimen was collected. The following minimum precautions shall be taken to ensure that unadulterated specimens are obtained and correctly identified:

(1) To deter the dilution of specimens at the collection site, toilet bluing agents

shall be placed in toilet tanks wherever possible, so the reservoir of water in the toilet bowl always remains blue. Where practicable, there shall be no other source of water (e.g., no shower or sink) in the enclosure where urination occurs. If there is another source of water in the enclosure, it shall be effectively secured or monitored to ensure it is not used (undetected) as a source for diluting the specimen.

(2) When an individual arrives at the collection site, the collection site person shall ensure that the individual is positively identified as the employee selected for testing (e.g., through presentation of photo identification or identification by the employer's representative). If the individual's identity cannot be established, the collection site person shall not proceed with the collection.

(3) If the individual fails to arrive at the assigned time, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(4) The collection site person shall ask the individual to remove any unnecessary outer garments such as a coat or jacket that might conceal items or substances that could be used to tamper with or adulterate the individual's urine specimen. The collection site person shall ensure that all personal belongings such as a purse or briefcase remain with the outer garments. The individual may retain his or her wallet.

(5) The individual shall be instructed to wash and dry his or her hands prior to urination.

(6) After washing hands, the individual shall remain in the presence of the collection site person and shall not have access to any water fountain, faucet, soap dispenser, cleaning agent or any other materials which could be used to adulterate the specimen.

(7) The individual may provide his/her specimen in the privacy of a stall or otherwise partitioned areas that allows for individual privacy.

(8) The collection site person shall note any unusual behavior or appearance on the urine custody and control form.

(9) In the exceptional event that an employer-designated collection site is not accessible and there is an immediate requirement for specimen collection (e.g., an accident investigation), a public rest room may be used according to the following procedures: A collection site person of the same gender as the individual shall accompany the individual into the public rest room which shall be made secure during the collection procedure. If possible, a toilet

bluing agent shall be placed in the bowl and any accessible toilet tank. The collection site person shall remain in the rest room, but outside the stall, until the specimen is collected. If no bluing agent is available to deter specimen dilution, the collection site person shall instruct the individual not to flush the toilet until the specimen is delivered to the collection site person. After the collection site person has possession of the specimen, the individual will be instructed to flush the toilet and to participate with the collection site person in completing the chain of custody procedures.

(10) Upon receiving the specimen from the individual, the collection site person shall determine that it contains at least 60 milliliters of urine. If there is less than 60 milliliters of urine in the container, additional urine shall be collected in a separate container to reach a total of 60 milliliters. (The temperature of the partial specimen in each separate container shall be measured in accordance with paragraph (f)(12) of this section, and the partial specimens shall be combined in one container.) The individual may be given a reasonable amount of liquid to drink for this purpose (e.g., a glass of water). If the individual fails for any reason to provide 60 milliliters of urine, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(11) After the specimen has been provided and submitted to the collection site person, the individual shall be allowed to wash his or her hands.

(12) Immediately after the specimen is collected, the collection site person shall measure the temperature of the specimen. The temperature measuring device used must accurately reflect the temperature of the specimen and not contaminate the specimen. The time from urination to temperature measure is critical and in no case shall exceed 4 minutes.

(13) If the temperature of a specimen is outside the range of 32.5°–37.7° C/ 90.5°–99.8° F, that is a reason to believe that the individual may have altered or substituted the specimen, and another specimen shall be collected under direct observation of a same gender collection site person and both specimens shall be forwarded to the laboratory for testing. An individual may volunteer to have his or her oral temperature taken to provide evidence to counter the reason to believe the individual may have altered or substituted the specimen caused by the specimen's temperature falling outside the prescribed range.

(14) Immediately after the specimen is collected, the collection site person shall also inspect the specimen to determine its color and look for any signs of contaminants. Any unusual findings shall be noted on the urine custody and control form.

(15) All specimens suspected of being adulterated shall be forwarded to the laboratory for testing.

(16) Whenever there is reason to believe that a particular individual has altered or substituted the specimen as described in paragraph (e)(2)(i) and (iii) of this section, a second specimen shall be obtained as soon as possible under the direct observation of a same gender collection site person.

(17) Both the individual being tested and the collection site person shall keep the specimen in view at all times prior to its being sealed and labeled. As provided below, the specimen shall be sealed (by placement of a tamperproof seal over the bottle cap and down the sides of the bottle) and labeled in the presence of the employee. If the specimen is transferred to a second bottle, the collection site person shall request the individual to observe the transfer of the specimen and the placement of the tamperproof seal over the bottle cap and down the sides of the bottle.

(18) The collection site person and the individual shall be present at the same time during procedures outlined in paragraphs (f)(19)-(f)(22) of this section.

(19) The collection site person shall place securely on the bottle an identification label which contains the date, the individual's specimen number, and any other identifying information provided or required by the employer. If separate from the label, the tamperproof seal shall also be applied.

(20) The individual shall initial the identification label on the specimen bottle for the purpose of certifying that it is the specimen collected from him or her.

(21) The collection site person shall enter on the urine custody and control form all information identifying the specimen. The collection site person shall sign the urine custody and control form certifying that the collection was accomplished according to the instructions provided.

(22) (i) The individual shall be asked to read and sign a statement on the urine custody and control form certifying that the specimen identified as having been collected from him or her is in fact that specimen he or she provided.

(ii) The individual shall be provided an opportunity to set forth on the urine custody and control form information

concerning medications taken or administered in the past 30 days.

(iii) When specified by DOT agency regulation or required by the collection site (other than an employer site) or by the laboratory, the employee may be required to sign a consent or release form authorizing the collection of the specimen, analysis of the specimen for designated controlled substances, and release of the results to the employer. The employee may not be required to waive liability with respect to negligence on the part of any person participating in the collection, handling or analysis of the specimen or to indemnify any person for the negligence of others.

(23) A higher level supervisor of the collection site person, or a designated employer representative, shall review and concur in advance with any decision by a collection site person to obtain a specimen under the direct observation of a same gender collection site person based upon the circumstances described paragraph (e)(2) of this section.

(24) The collection site person shall complete the chain of custody portion of the urine custody and control form to indicate receipt from the employee and shall certify proper completion of the collection.

(25) The urine specimen and chain of custody form are now ready for shipment. If the specimen is not immediately prepared for shipment, it shall be appropriately safeguarded during temporary storage.

(26)(i) While any part of the above chain of custody procedures is being performed, it is essential that the urine specimen and custody documents be under the control of the involved collection site person. If the involved collection site person leaves his or her work station momentarily, the specimen and urine custody and control form shall be taken with him or her or shall be secured. After the collection site person returns to the work station, the custody process will continue. If the collection site person is leaving for an extended period of time, the specimen shall be packaged for mailing before he or she leaves the site.

(ii) The collection site person shall not leave the collection site in the interval between presentation of the specimen by the employee and securement of the sample with an identifying label bearing the employee's specimen identification number (shown on the urine custody and control form) and seal initialed by the employee. If it becomes necessary for the collection site person to leave the site during this interval, the collection

shall be nullified and (at the election of the employer) a new collection begun.

(g) *Collection control.* To the maximum extent possible, collection site personnel shall keep the individual's specimen bottle within sight both before and after the individual has urinated. After the specimen is collected, it shall be properly sealed and labeled. The urine custody and control form shall be used for maintaining control and accountability of each specimen from the point of collection to final disposition of the specimen. The date and purpose shall be documented on an approval chain of custody form each time a specimen is handled or transferred and every individual in the chain shall be identified. Every effort shall be made to minimize the number of persons handling specimens.

(h) *Transportation to laboratory.* Collection site personnel shall arrange to ship the collected specimens to the drug testing laboratory. The specimens shall be placed in containers designed to minimize the possibility of damage during shipment (e.g., specimen boxes and/or padded mailers); and those containers shall be securely sealed to eliminate the possibility of undetected tampering. On the tape sealing the container, the collection site person shall sign and enter the date specimens were sealed in the containers for shipment. The collection site person shall ensure that the chain of custody documentation is attached to each container sealed for shipment to the drug testing laboratory.

(i) *Failure to cooperate.* If the employee refuses to cooperate with the collection process (e.g., refusal to provide a complete specimen, complete paperwork, initial specimen) the collection site person shall inform the employer representative and shall document the non-cooperation on the urine custody and control form.

#### § 40.27 Laboratory personnel.

(a) *Day-to-day management.* (1) The laboratory shall have a qualified individual to assume professional, organizational, educational, and administrative responsibility for the laboratory's urine drug testing facility.

(2) This individual shall have documented scientific qualifications in analytical forensic toxicology. Minimum qualifications are:

(i) Certification as a laboratory director by the State in forensic or clinical laboratory toxicology; or

(ii) A Ph.D. in one of the natural sciences with an adequate undergraduate and graduate education

in biology, chemistry, and pharmacology or toxicology, or

(iii) Training and experience comparable to a Ph.D. in one of the natural sciences, such as a medical or scientific degree with additional training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology; and

(iv) In addition to the requirements in paragraph (a)(2) (i), (ii), and (iii) of this section, minimum qualifications also require:

(A) Appropriate experience in analytical forensic toxicology including experience with the analysis of biological material for drugs of abuse, and

(B) Appropriate training and/or experience in forensic applications of analytical toxicology, e.g., publications, court testimony, research concerning analytical toxicology of drugs of abuse, or other factors which qualify the individual as an expert witness in forensic toxicology.

(3) This individual shall be engaged in and responsible for the day-to-day management of the drug testing laboratory even where another individual has overall responsibility for an entire multispecialty laboratory.

(4) This individual shall be responsible for ensuring that there are enough personnel with adequate training and experience to supervise and conduct the work of the drug testing laboratory. He or she shall assure the continued competency of laboratory personnel by documenting their inservice training, reviewing their work performance, and verifying their skills.

(5) This individual shall be responsible for the laboratory's having a procedure manual which is complete, up-to-date, available for personnel performing tests, and followed by those personnel. The procedure manual shall be reviewed, signed, and dated by this responsible individual whenever procedures are first placed into use or changed or when a new individual assumes responsibility for management of the drug testing laboratory. Copies of all procedures and dates on which they are in effect shall be maintained. (Specific contents of the procedure manual are described in § 40.29(n)(1).)

(6) This individual shall be responsible for maintaining a quality assurance program to assure the proper performance and reporting of all test results; for maintaining acceptable analytical performance for all controls and standards; for maintaining quality control testing; and for assuring and documenting the validity, reliability, accuracy, precision, and performance

characteristics of each test and test system.

(7) This individual shall be responsible for taking all remedial actions necessary to maintain satisfactory operation and performance of the laboratory in response to quality control systems not being within performance specifications, errors in result reporting or in analysis of performance testing results. This individual shall ensure that sample results are not reported until all corrective actions have been taken and he or she can assure that the tests results provided are accurate and reliable.

(b) *Test validation.* The laboratory's urine drug testing facility shall have a qualified individual(s) who reviews all pertinent data and quality control results in order to attest to the validity of the laboratory's test reports. A laboratory may designate more than one person to perform this function. This individual(s) may be any employee who is qualified to be responsible for day-to-day management or operation of the drug testing laboratory.

(c) *Day-to-day operations and supervision of analysts.* The laboratory's urine drug testing facility shall have an individual to be responsible for day-to-day operations and to supervise the technical analysts. This individual(s) shall have at least a bachelor's degree in the chemical or biological sciences or medical technology or equivalent. He or she shall have training and experience in the theory and practice of the procedures used in the laboratory, resulting in his or her thorough understanding of quality control practices and procedures; the review, interpretation, and reporting of test results; maintenance of chain of custody; and proper remedial actions to be taken in response to test systems being out of control limits or detecting aberrant test or quality control results.

(d) *Other personnel.* Other technicians or nontechnical staff shall have the necessary training and skills for the tasks assigned.

(e) *Training.* The laboratory's urine drug testing program shall make available continuing education programs to meet the needs of laboratory personnel.

(f) *Files.* Laboratory personnel files shall include: resume of training and experience; certification or license, if any; references; job descriptions; records of performance evaluation and advancement; incident reports; and results of tests which establish employee competency for the position he or she holds, such as a test for color blindness, if appropriate.

#### § 40.29 Laboratory analysis procedures.

(a) *Security and chain of custody.* (1) Drug testing laboratories shall be secure at all times. They shall have in place sufficient security measures to control access to the premises and to ensure that no unauthorized personnel handle specimens or gain access to the laboratory processes or to areas where records are stored. Access to these secured areas shall be limited to specifically authorized individuals whose authorization is documented. With the exception of personnel authorized to conduct inspections on behalf of Federal agencies for which the laboratory is engaged in urine testing or on behalf of DHHS, all authorized visitors and maintenance and service personnel shall be escorted at all times. Documentation of individuals accessing these areas, dates, and time of entry and purpose of entry must be maintained.

(2) Laboratories shall use chain of custody procedures to maintain control and accountability of specimens from receipt through completion of testing, reporting of results, during storage, and continuing until final disposition of specimens. The date and purpose shall be documented on an appropriate chain of custody form each time a specimen is handled or transferred, and every individual in the chain shall be identified. Accordingly, authorized technicians shall be responsible for each urine specimen or aliquot in their possession and shall sign and complete chain of custody forms for those specimens or aliquots as they are received.

(b) *Receiving.* (1) When a shipment of specimens is received, laboratory personnel shall inspect each package for evidence of possible tampering and compare information on specimen bottles within each package to the information on the accompanying chain of custody forms. Any direct evidence of tampering or discrepancies in the information on specimen bottles and the employer's chain of custody forms attached to the shipment shall be immediately reported to the employer and shall be noted on the laboratory's chain of custody form which shall accompany the specimens while they are in the laboratory's possession.

(2) Specimen bottles will normally be retained within the laboratory's accession area until all analyses have been completed. Aliquots and the laboratory's chain of custody forms shall be used by laboratory personnel for conducting initial and confirmatory tests.

(c) *Short-term refrigerated storage.* Specimens that do not receive an initial

test within 7 days of arrival at the laboratory shall be placed in secure refrigeration units. Temperatures shall not exceed 6°C. Emergency power equipment shall be available in case of prolonged power failure.

(d) *Specimen processing.* Laboratory facilities for urine drug testing will normally process specimens by grouping them into batches. The number of specimens in each batch may vary significantly depending on the size of the laboratory and its workload. When conducting either initial or confirmatory tests, every batch shall contain an appropriate number of standards for calibrating the instrumentation and a minimum of 10 percent controls. Both quality control and blind performance test samples shall appear as ordinary samples to laboratory analysts.

(e) *Initial test.* (1) The initial test shall use an immunoassay which meets the requirements of the Food and Drug Administration for commercial distribution. The following initial cutoff levels shall be used when screening specimens to determine whether they are negative for these five drugs or classes of drugs:

	Initial test Level (ng/ml)
Marijuana metabolites .....	100
Cocaine metabolites .....	300
Opiate metabolites .....	* 300
Phencyclidine .....	25
Amphetamines .....	1,000

\* 25ng/ml if immunoassay specific for free morphine.

(2) These test levels are subject to change by the Department of Health and Human Services as advances in technology or other considerations warrant identification of these substances at other concentrations. Initial test methods and testing levels for other drugs shall be submitted in writing by the employer for the written approval of the DOT Agency under that agency's regulations.

(f) *Confirmatory test.* (1) All specimens identified as positive on the initial test shall be confirmed using gas chromatography/mass spectrometry (GC/MS) techniques at the cutoff values listed in this paragraph for each drug. All confirmations shall be by quantitative analysis. Concentrations which exceed the linear region of the standard curve shall be documented in the laboratory record as "greater than highest standard curve value."

	Confirmatory test level (ng/ml)
Marijuana metabolite <sup>1</sup> .....	15
Cocaine metabolite <sup>2</sup> .....	150
Opiates: .....	
Morphine .....	300
Codeine .....	300
Phencyclidine .....	25
Amphetamines: .....	
Amphetamine .....	500
Methamphetamine .....	500

<sup>1</sup> Delta-9-tetrahydrocannabinol-9-carboxylic acid.

<sup>2</sup> Benzoylcegonine.

(2) These test levels are subject to change by the Department of Health and Human Services as advances in technology or other considerations warrant identification of these substances at other concentrations. Confirmatory test methods and testing levels for other drugs shall be submitted in writing by the employer for the written approval of the DOT agency as provided in that agency's regulations.

(g) *Reporting results.* (1) The laboratory shall report test results to the employer's Medical Review Officer within an average of 5 working days after receipt of the specimen by the laboratory. Before any test result is reported (the results of initial tests, confirmatory tests, or quality control data), it shall be reviewed and the test certified as an accurate report by the responsible individual. The report shall identify the drugs/metabolites tested for, whether positive or negative, and the cutoff for each, the specimen number assigned by the employer, and the drug testing laboratory specimen identification number (accession number). The results (positive and negative) for all specimens submitted at the same time to the laboratory shall be reported back to the Medical Review Officer at the same time.

(2) The laboratory shall report as negative all specimens which are negative on the initial test or negative on the confirmatory test. Only specimens confirmed positive shall be reported positive for a specific drug.

(3) The Medical Review Officer may request from the laboratory and the laboratory shall provide quantitation of test results. The Medical Review Officer may not disclose quantitation of test results to the employer but shall report only whether the test was positive or negative.

(4) The laboratory may transmit results to the Medical Review Officer by various electronic means (for example, teleprinters, facsimile, or computer) in a manner designed to ensure confidentiality of the information. Results may not be provided verbally by

telephone. The laboratory and employer must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(5) The laboratory shall send only to the Medical Review Officer the original or a certified true copy of the urine custody and control form (part 1), which shall be signed (after the required certification block) by the individual responsible for day-to-day management of the drug testing laboratory or the individual responsible for attesting to the validity of the test reports, and attached to which shall be a copy of the test report.

(6) The laboratory shall provide to the employer official responsible for coordination of the drug-free workplace program a monthly statistical summary of urinalysis testing of the employer's employees and shall not include in the summary any personal identifying information. Initial and confirmation data shall be included from test results reported within that month. Normally this summary shall be forwarded by registered or certified mail not more than 14 calendar days after the end of the month covered by the summary. The summary shall contain the following information:

(i) *Initial testing:*

(A) Number of specimens received;

(B) Number of specimens reported out; and

(C) Number of specimens screened positive for:

Marijuana metabolites  
Cocaine metabolites  
Opiate metabolites  
Phencyclidine  
Amphetamines

(ii) *Confirmatory testing:*

(A) Number of specimens received for confirmation;

(B) Number of specimens confirmed positive for:

Marijuana metabolite  
Cocaine metabolite  
Morphine, codeine  
Phencyclidine  
Amphetamine  
Methamphetamine

(7) The laboratory shall make available copies of all analytical results for employer drug testing programs when requested by DOT or any DOT agency with regulatory authority over the employer.

(8) Unless otherwise instructed by the employer in writing, all records pertaining to a given urine specimen shall be retained by the drug testing laboratory for a minimum of 2 years.

(h) *Long-term storage.* Long-term frozen storage ( $-20^{\circ}\text{C}$  or less) ensures that positive urine specimens will be available for any necessary retest during administrative or disciplinary proceedings. Drug testing laboratories shall retain and place in properly secured long-term frozen storage for a minimum of 1 year all specimens confirmed positive. Within this 1-year period an employer (or other person designated in a DOT agency regulation) may request the laboratory to retain the specimen for an additional period of time, but if no such request is received the laboratory may discard the specimen after the end of 1 year, except that the laboratory shall be required to maintain any specimens under legal challenge for an indefinite period.

(i) *Retesting specimens.* Because some analytes deteriorate or are lost during freezing and/or storage, quantitation for a retest is not subject to a specific cutoff requirement but must provide data sufficient to confirm the presence of the drug or metabolite.

(j) *Subcontracting.* Drug testing laboratories shall not subcontract and shall perform all work with their own personnel and equipment. The laboratory must be capable of performing testing for the five classes of drugs (marijuana, cocaine, opiates, phencyclidine, and amphetamines) using the initial immunoassay and confirmatory GC/MS methods specified in this part procedures. This paragraph does not prohibit subcontracting of laboratory analysis if specimens are sent directly from the collection site to the subcontractor, the subcontractor is a laboratory certified by DHHS as required in this part, the subcontractor performs all analysis and provides storage required under this part, the subcontractor is responsible to the employer for compliance with this part and applicable DOT agency regulations as if it were the prime contractor, and other relevant provisions of this part are observed.

(k) *Laboratory facilities.* (1) Laboratory facilities shall comply with applicable provisions of any State licensure requirements.

(2) Laboratories certified in accordance with DHHS Mandatory Guidelines for Federal Workplace Drug Testing Programs must have the capability, at the same laboratory premises, of performing initial and confirmatory tests for each drug or metabolite for which service is offered.

(l) *Inspections.* The Secretary, a DOT agency, any employer utilizing the laboratory, DHHS or any organization performing laboratory certification on behalf of DHHS reserve the right to

inspect the laboratory at any time. Employer contracts with laboratories for drug testing, as well as contracts for collection site services, shall permit the employer and the DOT agency of jurisdiction (directly or through an agency) to conduct unannounced inspections.

(m) *Documentation.* The drug testing laboratories shall maintain and make available for at least 2 years documentation of all aspects of the testing process. This 2-year period may be extended upon written notification by a DOT agency or by any employer for which laboratory services are being provided. The required documentation shall include personnel files on all individuals authorized to have access to specimens; chain of custody documents; quality assurance/quality control records; procedure manuals; all test data (including calibration curves and any calculations used in determining test results); reports; performance records on performance testing; performance on certification inspections; and hard copies of computer-generated data. The laboratory shall be required to maintain documents for any specimen under legal challenge for an indefinite period.

(n) *Additional requirements for certified laboratories.*—(1) *Procedure manual.* Each laboratory shall have a procedure manual which includes the principles of each test, preparation of reagents, standards and controls, calibration procedures, derivation of results, linearity of methods, sensitivity of the methods, cutoff values, mechanisms for reporting results, controls, criteria for unacceptable specimens and results, remedial actions to be taken when the test systems are outside of acceptable limits, reagents and expiration dates, and references. Copies of all procedures and dates on which they are in effect shall be maintained as part of the manual.

(2) *Standards and controls.* Laboratory standards shall be prepared with pure drug standards which are properly labeled as to content and concentration. The standards shall be labeled with the following dates: when received; when prepared or opened; when placed in service; and expiration date.

(3) *Instruments and equipment.* (i) Volumetric pipettes and measuring devices shall be certified for accuracy or be checked by gravimetric, colorimetric, or other verification procedure. Automatic pipettes and dilutors shall be checked for accuracy and reproducibility before being placed in service and checked periodically thereafter.

(ii) There shall be written procedures for instrument set-up and normal operation, a schedule for checking critical operating characteristics for all instruments, tolerance limits for acceptable function checks and instructions for major trouble shooting and repair. Records shall be available on preventive maintenance.

(4) *Remedial actions.* There shall be written procedures for the actions to be taken when systems are out of acceptable limits or errors are detected. There shall be documentation that these procedures are followed and that all necessary corrective actions are taken. There shall also be in place systems to verify all stages of testing and reporting and documentation that these procedures are followed.

(5) *Personnel available to testify at proceedings.* A laboratory shall have qualified personnel available to testify in an administrative or disciplinary proceeding against an employee when that proceeding is based on positive urinalysis results reported by the laboratory.

#### § 40.31 Quality assurance and quality control.

(a) *General.* Drug testing laboratories shall have a quality assurance program which encompasses all aspects of the testing process including but not limited to specimen acquisition, chain of custody, security and reporting of results, initial and confirmatory testing, and validation of analytical procedures. Quality assurance procedures shall be designed, implemented, and reviewed to monitor the conduct of each step of the process of testing for drugs.

(b) *Laboratory quality control requirements for initial tests.* Each analytical run of specimens to be screened shall include:

(1) Urine specimens certified to contain no drug;

(2) Urine specimens fortified with known standards; and

(3) Positive controls with the drug or metabolite at or near the threshold (cutoff).

In addition, with each batch of samples a sufficient number of standards shall be included to ensure and document the linearity of the assay method over time in the concentration area of the cutoff. After acceptable values are obtained for the known standards, those values will be used to calculate sample data. Implementation of procedures to ensure that carryover does not contaminate the testing of an individual's specimen shall be documented. A minimum of 10 percent of all test samples shall be quality control specimens. Laboratory

quality control samples, prepared from spiked urine samples of determined concentration shall be included in the run and should appear as normal samples to laboratory analysts. One percent of each run, with a minimum of at least one sample, shall be the laboratory's own quality control samples.

(c) Laboratory quality control requirements for confirmation tests. Each analytical run of specimens to be confirmed shall include:

- (1) Urine specimens certified to contain no drug;
- (2) Urine specimens fortified with known standards; and
- (3) Positive controls with the drug or metabolite at or near the threshold (cutoff).

The linearity and precision of the method shall be periodically documented. Implementation of procedures to ensure that carryover does not contaminate the testing of an individual's specimen shall also be documented.

(d) Employer blind performance test procedures. (1) Employers shall purchase drug testing services only from laboratories certified by DHHS or a DHHS-recognized certification program in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs. Laboratory participation is encouraged in other performance testing surveys by which the laboratory's performance is compared with peers and reference laboratories.

(2) (i) During the initial 90-day period of any new drug testing program, each employer shall submit blind performance test specimens to each laboratory it contracts with in the amount of at least 50 percent of the total number of samples submitted (up to a maximum of 500 samples) and thereafter a minimum of 10 percent of all samples (to a maximum of 250) submitted per quarter.

(ii) These blind performance testing requirements shall not apply to an employer that submits fewer than 1,000 employee specimens per year for analysis under one or more DOT agency regulations requiring compliance with this part, if such employer utilizes a laboratory that is currently subject to blind performance testing under this part or the DHHS Mandatory Guidelines for Federal Workplace Drug Testing Programs by a Federal agency or by another transportation employer required by this section to perform such blind performance testing for the substances for which the specimen is to be tested.

(3) Approximately 80 percent of the blind performance test samples shall be blank (i.e., certified to contain no drug) and the remaining samples shall be positive for one or more drugs per sample in a distribution such that all the drugs to be tested are included in approximately equal frequencies of challenge. The positive samples shall be spiked only with those drugs for which the employer is testing. This paragraph shall not be construed to prohibit spiking of other (potentially interfering) compounds, as technically appropriate, in order to verify the specificity of a particular assay.

(4) The DOT agency concerned shall investigate, or shall refer to DHHS for investigation, any unsatisfactory performance testing result and, based on this investigation, the laboratory shall take action to correct the cause of the unsatisfactory performance test result. A record shall be made of the investigative findings and the corrective action taken by the laboratory, and that record shall be dated and signed by the individuals responsible for the day-to-day management and operation of the drug testing laboratory. Then the DOT agency shall send the document to the employer as a report of the unsatisfactory performance testing incident. The DOT agency shall ensure notification of the finding to DHHS.

(5) Should a false positive error occur on a blind performance test specimen and the error is determined to be an administrative error (clerical, sample mixup, etc.), the employer shall promptly notify the DOT agency concerned. The DOT agency and the employer shall require the laboratory to take corrective action to minimize the occurrence of the particular error in the future; and, if there is reason to believe the error could have been systematic, the DOT agency may also require review and reanalysis of previously run specimens.

(6) Should a false positive error occur on a blind performance test specimen and the error is determined to be a technical or methodological error, the employer shall instruct the laboratory to submit all quality control data from the batch of specimens which included the false positive specimen to the DOT agency concerned. In addition, the laboratory shall retest all specimens analyzed positive for that drug or metabolite from the time of final resolution of the error back to the time of the last satisfactory performance test cycle. This retesting shall be documented by a statement signed by the individual responsible for day-to-day management of the laboratory's urine drug testing. The DOT agency

concerned may require an on-site review of the laboratory which may be conducted unannounced during any hours of operation of the laboratory. Based on information provided by the DOT agency, DHHS has the option of revoking or suspending the laboratory's certification or recommending that no further action be taken if the case is one of less serious error in which corrective action has already been taken, thus reasonably assuring that the error will not occur again.

#### § 40.33 Reporting and review of results.

(a) *Medical Review Officer shall review results.* An essential part of the drug testing program is the final review of results. A positive test result does not automatically identify an employee/applicant as having used drugs in violation of a DOT agency regulation. An individual with a detailed knowledge of possible alternate medical explanations is essential to the review of results. This review shall be performed by the Medical Review Officer prior to the transmission of results to employer administrative officials.

(b) *Medical Review Officer—qualifications and responsibilities.* The Medical Review Officer shall be a licensed physician with knowledge of substance abuse disorders and may be an employee of the transportation employer or a private physician retained for this purpose. The role of the Medical Review Officer is to review and interpret positive test results obtained through the employer's testing program. In carrying out this responsibility, the Medical Review Officer shall examine alternate medical explanations for any positive test result. This action could include conducting a medical interview with the individual, review of the individual's medical history, or review of any other relevant biomedical factors. The Medical Review Officer shall review all medical records made available by the tested individual when a confirmed positive test could have resulted from legally prescribed medication. The Medical Review Officer shall not, however, consider the results of urine samples that are not obtained or processed in accordance with this part.

(c) *Positive test result.* Prior to making a final decision to verify a positive test result, the Medical Review Officer shall give the individual an opportunity to discuss the test result with him or her. Following verification of a positive test result, the Medical Review Officer shall, as provided in the employer's policy, refer the case to the employer employee assistance or rehabilitation program, if

applicable, to the management official empowered to recommend or take administrative action (or the official's designated agent), or both.

(d) *Verification for opiates; review for prescription medication.* Before the Medical Review Officer verifies a confirmed positive result for opiates, he or she shall determine that there is clinical evidence—in addition to the urine test—of unauthorized use of any opium, opiate, or opium derivative (e.g., morphine/codeine). (This requirement does not apply if the employer's GC/MS confirmation testing for opiates confirms the presence of 6-monoacetylmorphine.)

(e) *Reanalysis authorized.* Should any question arise as to the accuracy or validity of a positive test result, only the Medical Review Officer is authorized to order a reanalysis of the original sample and such retests are authorized only at laboratories certified by DHHS. The Medical Review Officer shall authorize a reanalysis of the original sample on timely request of the employee, as provided in applicable DOT agency regulations.

(f) *Result consistent with legal drug use.* If the Medical Review Officer determines there is a legitimate medical explanation for the positive test result, the Medical Review Officer shall report the test result to the employer as negative.

(g) *Result scientifically insufficient.* Additionally, the Medical Review Officer, based on review of inspection reports, quality control data, multiple samples, and other pertinent results, may determine that the result is scientifically insufficient for further action and declare the test specimen negative. In this situation the Medical Review Officer may request reanalysis of the original sample before making this decision. (The Medical Review Officer may request that reanalysis be performed by the same laboratory or, as provided in § 40.33(e), that an aliquot of the original specimen be sent for reanalysis to an alternate laboratory which is certified in accordance with the DHHS Guidelines.) The laboratory shall assist in this review process as requested by the Medical Review Officer by making available the individual responsible for day-to-day management of the urine drug testing laboratory or other employee who is a forensic toxicologist or who has equivalent forensic experience in urine drug testing, to provide specific consultation as required by the employer. The employer shall include in its annual report to the DOT agency a summary of any negative findings based on scientific insufficiency but shall not

include any personal identifying information in such reports.

#### § 40.35 Protection of employee records.

Employer contracts with laboratories shall require that the laboratory maintain employee test records in confidence, as provided in DOT agency regulations.

#### § 40.37 Individual access to test and laboratory certification results.

Any employee who is the subject of a drug test conducted under this part shall, upon written request, have access to any records relating to his or her drug test and any records relating to the results of any relevant certification, review, or revocation-of-certification proceedings.

### Subpart C—Certification of Laboratories Engaged in Urine Drug Testing

#### § 40.41 Use of DHHS-certified laboratories.

Employers subject to this part shall use only laboratories certified under the DHHS Mandatory Guidelines for Federal Workplace Drug Testing Programs, 53 FR 11970, April 11, 1988, and subsequent amendments thereto. DHHS certification standards are set forth in Appendix A to this part for information and reference. Information concerning the current certification status of laboratories is available from: the Office of Workplace Initiatives, National Institute on Drug Abuse, 5600 Fishers Lane, Rockville, Maryland 20857.

### Appendix A to Part 40—DHHS Laboratory Certification Standards

**Note:** Reproduced below is subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs issued by DHHS. Cross-references are to sections of those DHHS Guidelines. Equivalent provisions in this part may be determined by reference to the following table:

DHHS Guidelines:		Part 40
Section 1.1.....	§ 40.1	
Section 1.2.....	§ 40.2	
Section 2.1.....	§ 40.21	
Section 2.2.....	§ 40.25	
Section 2.3.....	§ 40.27	
Section 2.4.....	§ 40.29	
Section 2.5.....	§ 40.31	
Section 2.6.....		
Section 2.7.....	§ 40.33	
Section 2.8.....	§ 40.35	
Section 2.9.....	§ 40.37	

### Subpart C—Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies

#### Section 3.1 Introduction.

Urine drug testing is a critical component of efforts to combat drug abuse in our society. Many laboratories are familiar with good laboratory practices but may be unfamiliar with the special procedures required when drug test results are used in the employment context. Accordingly, the following are minimum standards to certify laboratories engaged in urine drug testing for Federal agencies. Certification, even at the highest level, does not guarantee accuracy of each result reported by a laboratory conducting urine drug testing for Federal agencies. Therefore, results from laboratories certified under these Guidelines must be interpreted with a complete understanding of the total collection, analysis, and reporting process before a final conclusion is made.

#### Section 3.2 Goals and Objectives of Certification.

(a) *Uses of Urine Drug Testing.* Urine drug testing is an important tool to identify drug users in a variety of settings. In the proper context, urine drug testing can be used to deter drug abuse in general. To be a useful tool, the testing procedure must be capable of detecting drugs or their metabolites at concentrations indicated in section 2.4 (e) and (f).

(b) *Need to Set Standards; Inspections.* Reliable discrimination between the presence, or absence, of specific drugs or their metabolites is critical, not only to achieve the goals of the testing program but to protect the rights of the Federal employees being tested. Thus, standards have been set which laboratories engaged in Federal employee urine drug testing must meet in order to achieve maximum accuracy of test results. These laboratories will be evaluated by the Secretary or the Secretary's designee as defined in section 1.2 in accordance with these Guidelines. The qualifying evaluation will involve three rounds of performance testing plus on-site inspection. Maintenance of certification requires participation in an every-other-month performance testing program plus periodic, on-site inspections. One inspection following successful completion of a performance testing regimen is required for initial certification. This must be followed by a second inspection within 3 months, after which biannual inspections will be required to maintain certification.

(c) *Urine Drug Testing Applies Analytical Forensic Toxicology.* The possible impact of a positive test result on an individual's livelihood or rights, together with the possibility of a legal challenge of the result, sets this type of test apart from most clinical laboratory testing. In fact, urine drug testing should be considered a special application of analytical forensic toxicology. That is, in addition to the application of appropriate analytical methodology, the specimen must be treated as evidence, and all aspects of the testing procedure must be documented and available for possible court testimony. Laboratories engaged in urine drug testing for Federal agencies will require the services and

advice of a qualified forensic toxicologist, or individual with equivalent qualifications (both training and experience) to address the specific needs of the Federal drug testing program, including the demands of chain of custody of specimens, security, proper documentation of all records, storage of positive specimens for later or independent testing, presentation of evidence in court, and expert witness testimony.

### Section 3.3 General Certification Requirements.

A laboratory must meet all the pertinent provisions of these Guidelines in order to qualify for certification under these standards.

### Section 3.4 Capability to Test for Five Classes of Drugs.

To be certified, a laboratory must be capable of testing for at least the following five classes of drugs: marijuana, cocaine, opiates, amphetamines, and phencyclidine, using the initial immunoassay and quantitative confirmatory GC/MS methods specified in these Guidelines. The certification program will be limited to the five classes of drugs (section 2.1(a) (1) and (2)) and the methods (section 2.4 (e) and (f)) specified in these Guidelines. The laboratory will be surveyed and performance tested only for these methods and drugs. Certification of a laboratory indicates that any test result reported by the laboratory for the Federal Government meets the standards in these Guidelines for the five classes of using the methods specified. Certified laboratories must clearly inform non-Federal clients when procedures followed for those clients conform to the standards specified in these Guidelines.

### Section 3.5 Initial and Confirmatory Capability at Same Site.

Certified laboratories shall have the capability, at the same laboratory site, of performing both initial immunoassays and confirmatory GC/MS tests (section 2.4(e) and (f)) for marijuana, cocaine, opiates, amphetamines, and phencyclidine and for any other drug or metabolite for which agency drug testing is authorized (section 2.1(a)(1) and (2)). All positive initial test results shall be confirmed prior to reporting them.

### Section 3.6 Personnel.

Laboratory personnel shall meet the requirements specified in section 2.3 of these Guidelines. These Guidelines establish the exclusive standards for qualifying or certifying those laboratory personnel involved in urinalysis testing whose functions are prescribed by these Guidelines. A certification of a laboratory under these Guidelines shall be a determination that these qualification requirements have been met.

### Section 3.7 Quality Assurance and Quality Control.

Drug testing laboratories shall have a quality assurance program which encompasses all aspects of the testing process, including but not limited to specimen acquisition, chain of custody, security and

reporting of results, initial and confirmatory testing, and validation of analytical procedures. Quality control procedures shall be designed, implemented, and reviewed to monitor the conduct of each step of the process of testing for drugs as specified in section 2.5 of these Guidelines.

### Section 3.8 Security and Chain of Custody.

Laboratories shall meet the security and chain of custody requirements provided in section 2.4(a).

### Section 3.9 One-Year Storage for Confirmed Positives.

All confirmed positive specimens shall be retained in accordance with the provisions of section 2.4(h) of these Guidelines.

### Section 3.10 Documentation.

The Laboratory shall maintain and make available for at least 2 years documentation in accordance with the specifications in section 2.4(m).

### Section 3.11 Reports.

The laboratory shall report test results in accordance with the specifications in section 2.4(g).

### Section 3.12 Certification.

(a) *General.* The Secretary may certify any laboratory that meets the standards in these Guidelines to conduct urine drug testing. In addition, the Secretary may consider to be certified any laboratory that is certified by a DHHS-recognized certification program in accordance with these Guidelines.

(b) *Criteria.* In determining whether to certify a laboratory or to accept the certification of a DHHS-recognized certification program in accordance with these Guidelines, the Secretary shall consider the following criteria:

- (1) The adequacy of the laboratory facilities;
- (2) The expertise and experience of the laboratory personnel;
- (3) The excellence of the laboratory's quality assurance/quality control program;
- (4) The performance of the laboratory on any performance tests;
- (5) The laboratory's compliance with standards as reflected in any laboratory inspections; and
- (6) Any other factors affecting the reliability and accuracy of drug tests and reporting done by the laboratory.

### Section 3.13 Revocation.

(a) *General.* The Secretary shall revoke certification of any laboratory certified under these provisions or accept revocation by a DHHS-recognized certification program in accordance with these Guidelines if the Secretary determines that revocation is necessary to ensure the full reliability and accuracy of drug tests and the accurate reporting of test results.

(b) *Factors to Consider.* The Secretary shall consider the following factors in determining whether revocation is necessary:

- (1) Unsatisfactory performance in analyzing and reporting the results of drug tests; for example, a false positive error in reporting the results of an employee's drug test;

(2) Unsatisfactory participation in performance evaluations or laboratory inspections;

(3) A material violation of a certification standard or a contract term or other condition imposed on the laboratory by a Federal agency using the laboratory's services;

(4) Conviction for any criminal offense committed as an incident to operation of the laboratory; or

(5) Any other cause which materially affects the ability of the laboratory to ensure the full reliability and accuracy of drug tests and the accurate reporting of results.

(c) *Period and Terms.* The period and terms of revocation shall be determined by the Secretary and shall depend upon the facts and circumstances of the revocation and the need to ensure accurate and reliable drug testing of Federal employees.

### Section 3.14 Suspension.

(a) *Criteria.* Whenever the Secretary has reason to believe that revocation may be required and that immediate action is necessary in order to protect the interests of the United States and its employees, the Secretary may immediately suspend a laboratory's certification to conduct urine drug testing for Federal agencies. The Secretary may also accept suspension of certification by a DHHS-recognized certification program in accordance with these Guidelines.

(b) *Period and Terms.* The period and terms of suspension shall be determined by the Secretary and shall depend upon the facts and circumstances of the suspension and the need to ensure accurate and reliable drug testing of Federal employees.

### Section 3.15 Notice; Opportunity for Review.

(a) *Written Notice.* When a laboratory is suspended or the Secretary seeks to revoke certification, the Secretary shall immediately serve the laboratory with written notice of the suspension or proposed revocation by personal service or registered or certified mail, return receipt requested. This notice shall state the following:

- (1) The reasons for the suspension or proposed revocation;
- (2) The terms of the suspension or proposed revocation; and
- (3) The period of suspension or proposed revocation.

(b) *Opportunity for Informal Review.* The written notice shall state that the laboratory will be afforded an opportunity for an informal review of the suspension or proposed revocation if it so requests in writing within 30 days of the date of mailing or service of the notice. The review shall be by a person or persons designated by the Secretary and shall be based on written submissions by the laboratory and the Department of Health and Human Services and, at the Secretary's discretion, may include an opportunity for an oral presentation. Formal rules of evidence and procedures applicable to proceedings in a court of law shall not apply. The decision of the reviewing official shall be final.

(c) *Effective Date.* A suspension shall be effective immediately. A proposed revocation shall be effective 30 days after written notice is given or, if review is requested, upon the reviewing official's decision to uphold the proposed revocation. If the reviewing official decides not to uphold the suspension or proposed revocation, the suspension shall terminate immediately and any proposed revocation shall not take effect.

(d) *DHHS-Recognized Certification Program.* The Secretary's responsibility under this section may be carried out by a DHHS-recognized certification program in accordance with these Guidelines.

#### Section 3.16 Recertification.

Following the termination or expiration of any suspension or revocation, a laboratory may apply for recertification. Upon the submission of evidence satisfactory to the Secretary that the laboratory is in compliance with these Guidelines or any DHHS-recognized certification program in accordance with these Guidelines, and any other conditions imposed as part of the suspension or revocation, the Secretary may recertify the laboratory or accept the recertification of the laboratory by a DHHS-recognized certification program.

#### Section 3.17 Performance Test Requirement for Certification

(a) *An Initial and Continuing Requirement.* The performance testing program is a part of the initial evaluation of a laboratory seeking certification (both performance testing and laboratory inspection are required) and of the continuing assessment of laboratory performance necessary to maintain this certification.

(b) *Three Initial Cycles Required.* Successful participation in three cycles of testing shall be required before a laboratory is eligible to be considered for inspection and certification. These initial three cycles (and any required for recertification) can be compressed into a 3-month period (one per month).

(c) *Six Challenges Per Year.* After certification, laboratories shall be challenged every other month with one set of at least 10 specimens—a total of six cycles per year.

(d) *Laboratory Procedures Identical for Performance Test and Routine Employee Specimens.* All procedures associated with the handling and testing of the performance test specimens by the laboratory shall to the greatest extent possible be carried out in a manner identical to that applied to routine laboratory specimens, unless otherwise specified.

(e) *Blind Performance Test.* Any certified laboratory shall be subject to blind performance testing (see section 2.5(d)). Performance on blind test specimens shall be at the same level as for the open or non-blind performance testing.

(f) *Reporting—Open Performance Test.* The laboratory shall report results of open performance tests to the certifying organization in the same manner as specified in section 2.4(g)(2) for routine laboratory specimens.

#### Section 3.18 Performance Test Specimen Composition.

(a) *Description of the Drugs.* Performance test specimens shall contain those drugs and metabolites which each certified laboratory must be prepared to assay in concentration ranges that allow detection of the analyte by commonly used immunoassay screening techniques. These levels are generally in the range of concentrations which might be expected in the urine of recent drug users. For some drug analytes, the specimen composition will consist of the parent drug as well as major metabolites. In some cases, more than one drug class may be included in one specimen container, but generally no more than two drugs will be present in any one specimen in order to imitate the type of specimen which a laboratory normally encounters. For any particular performance testing cycle, the actual composition of kits going to different laboratories will vary but, within any annual period, all laboratories participating will have analyzed the same total set of specimens.

(b) *Concentrations.* Performance test specimens shall be spiked with the drug classes and their metabolites which are required for certification: marijuana, cocaine, opiates, amphetamines, and phenylcyclidine, with concentration levels set at least 20 percent above the cutoff limit for either the initial assay or the confirmatory test, depending on which is to be evaluated. Some performance test specimens may be identified for GC/MS assay only. Blanks shall contain less than 2 ng/ml of any of the target drugs. These concentration and drug types may be changed periodically in response to factors such as changes in detection technology and patterns of drug use.

#### Section 3.19 Evaluation of Performance Testing.

(a) *Initial Certification.* (1) An applicant laboratory shall not report any false positive result during performance testing for initial certification. Any false positive will automatically disqualify a laboratory from further consideration.

(2) An applicant laboratory shall maintain an overall grade level of 90 percent for the three cycles of performance testing required for initial certification, i.e., it must correctly identify and confirm 90 percent of the total drug challenges for each shipment. Any laboratory which achieves a score on any one cycle of the initial certification such that it can no longer achieve a total grade of 90 percent over the three cycles will be immediately disqualified from further consideration.

(3) An applicant laboratory shall obtain quantitative values for at least 80 percent of the total challenges which are  $\pm 20$  percent or  $\pm 2$  standard deviations of the calculated reference group mean (whichever is larger). Failure to achieve 80 percent will result in disqualification.

(4) An applicant laboratory shall not obtain any quantitative values that differ by more than 50 percent from the calculated reference group mean. Any quantitative values that differ by more than 50 percent will result in disqualification.

(5) For any individual drug, an applicant laboratory shall successfully detect and quantitate in accordance with paragraphs (a)(2), (a)(3), and (a)(4) of this section at least 50 percent of the total drug challenges. Failure to successfully quantitate at least 50 percent of the challenges for any individual drug will result in disqualification.

(b) *Ongoing Testing of Certified Laboratories.* (1) *False Positives and Procedures for Dealing with Them.* No false drug identifications are acceptable for any drugs for which a laboratory offers service. Under some circumstances a false positive test may result in suspension or revocation of certification. The most serious false positives are by drug class, such as reporting THC in a blank specimen or reporting cocaine in a specimen known to contain only opiates. Misidentifications within a class (e.g., codeine for morphine) are also false positives which are unacceptable in an appropriately controlled laboratory, but they are clearly less serious errors than misidentification of a class. The following procedures shall be followed when dealing with a false positive:

(i) The agency detecting a false positive error shall immediately notify the laboratory and the Secretary of any such error.

(ii) The laboratory shall provide the Secretary with a written explanation of the reasons for the error within 5 working days. If required by paragraph (b)(1)(v) below, this explanation shall include the submission of all quality control data from the batch of specimens that included the false positive specimen.

(iii) The Secretary shall review the laboratory's explanation within 5 working days and decide what further action, if any, to take.

(iv) If the error is determined to be an administrative error (clerical, sample mixup, etc.), the Secretary may direct the laboratory to take corrective action to minimize the occurrence of the particular error, in the future and, if there is reason to believe the error could have been systematic, may require the laboratory to review and reanalyze previously run specimens.

(v) If the error is determined to be a technical or methodological error, the laboratory shall submit to the Secretary all quality control data from the batch of specimens which included the false positive specimen. In addition, the laboratory shall retest all specimens analyzed positive by the laboratory from the time of final resolution of the error back to the time of the last satisfactory performance test cycle. This retesting shall be documented by a statement signed by the individual responsible for the day-to-day management of the laboratory's urine drug testing. Depending on the type of error which caused the false positive, this retesting may be limited to one analyte or may include any drugs a laboratory certified under these Guidelines must be prepared to assay. The laboratory shall immediately notify the agency if any result on a retest sample must be corrected because the criteria for a positive are not satisfied. The Secretary may suspend or revoke the laboratory's certification for all drugs or for only the drug or drug class in which the error occurred.

However, if the class is one of a less serious error for which effective corrections have already been made, thus reasonably assuring that the error will not occur again, the Secretary may decide to take no further action.

(vi) During the time required to resolve the error, the laboratory shall remain certified but shall have a designation indicating that a false positive result is pending resolution. If the Secretary determines that the laboratory's certification must be suspended or revoked, the laboratory's official status will become "Suspended" or "Revoked" until the suspension or revocation is lifted or any recertification process is complete.

(2) *Requirement to Identify and Confirm 90 Percent of Total Drug Challenges.* In order to remain certified, laboratories must successfully complete six cycles of performance testing per year. Failure of a certified laboratory to maintain a grade of 90 percent on any required performance test cycle, i.e., to identify 90 percent of the total drug challenges and to correctly confirm 90 percent of the total drug challenges, may result in suspension or revocation of certification.

(3) *Requirement to Quantitate 80 Percent of Total Drug Challenges at  $\pm 20$  Percent or  $\pm 2$  standard deviations.* Quantitative values obtained by a certified laboratory for at least 80 percent of the total drug challenges must be  $\pm 20$  percent or  $\pm 2$  standard deviations of the calculated reference group mean (whichever is larger).

(4) *Requirement to Quantitate within 50 Percent of Calculated Reference Group Mean.* No quantitative values obtained by a certified laboratory may differ by more than 50 percent from the calculated reference group mean.

(5) *Requirement to Successfully Detect and Quantitate 50 Percent of the Total Drug*

*Challenges for Any Individual Drug.* For any individual drug, a certified laboratory must successfully detect and quantitate in accordance with paragraphs (b)(2), (b)(3), and (b)(4) of this section at least 50 percent of the total drug challenges.

(6) *Procedures When Requirements in Paragraphs (b)(2)—(b)(5) of this Section Are Not Met.* If a certified laboratory fails to maintain a grade of 90 percent per test cycle after initial certification as required by paragraph (b)(2) of this section or if it fails to successfully quantitate results as required by paragraphs (b)(3), and (b)(4), or (b)(5) of this section, the laboratory shall be immediately informed that its performance fell under the 90 percent level or that it failed to successfully quantitate test results and how it failed to successfully quantitate. The laboratory shall be allowed 5 working days in which to provide any explanation for its unsuccessful performance, including administrative error or methodological error, and evidence that the source of the poor performance has been corrected. The Secretary may revoke or suspend the laboratory's certification or take no further action, depending on the seriousness of the errors and whether there is evidence that the source of the poor performance has been corrected and that current performance meets the requirements for a certified laboratory under these Guidelines. The Secretary may require that additional performance tests be carried out to determine whether the source of the poor performance has been removed. If the Secretary determines to suspend or revoke the laboratory's certification, the laboratory's official status will become "Suspended" or "Revoked" until the suspension or revocation is lifted or until any recertification process is complete.

(c) *80 Percent of Participating Laboratories Must Detect Drug.* A laboratory's

performance shall be evaluated for all samples for which drugs were spiked at concentrations above the specified performance test level unless the overall response from participating laboratories indicates that less than 80 percent of them were able to detect a drug.

(d) *Participation Required.* Failure to participate in a performance test or to participate satisfactorily may result in suspension or revocation of certification.

#### *Section 3.20 Inspections.*

Prior to laboratory certification under these Guidelines and at least twice a year after certification, a team of three qualified inspectors, at least two of whom have been trained as laboratory inspectors, shall conduct an on-site inspection of laboratory premises. Inspections shall document the overall quality of the laboratory setting for the purposes of certification to conduct urine drug testing. Inspection reports may also contain recommendations to the laboratory to correct deficiencies noted during the inspection.

#### *Section 3.21 Results of Inadequate Performance.*

Failure of a laboratory to comply with any aspect of these Guidelines may lead to revocation or suspension of certification as provided in sections 3.13 and 3.14 of these guidelines.

#### **Appendix B to Part 40—Urine Custody and Control Form**

The urine custody and control form shall meet the requirements of § 40.23. The following is a sample form that meets those requirements:

BILLING CODE 4910-62-M

## URINE CUSTODY AND CONTROL FORM

## STEP 1 -- TO BE COMPLETED BY EMPLOYEE/APPLICANT

Employee I.D. # \_\_\_\_\_ [PRE-PRINTED SPECIMEN I.D. #] Employer Name: \_\_\_\_\_  
 Social Security No. \_\_\_\_\_  
 or Employee No. \_\_\_\_\_

## STEP 2 -- TO BE COMPLETED BY EMPLOYER REPRESENTATIVE/OR COLLECTOR Reason for Test (Check One)

☐ Pre-employment ☐ Post Accident ☐ Random ☐ Periodic Medical  
☐ Other(Specify) \_\_\_\_\_

STEP 3 -- COLLECTOR MUST NOTE THAT TEMPERATURE OF SPECIMEN HAS BEEN READ. RECORD IF NOT WITHIN THE RANGE OF 32.5 - 37.7C/ 90.5 - 99.8 F: ☐ WITHIN RANGE

## STEP 4 -- TO BE INITIATED BY THE PERSON COLLECTING SPECIMEN AND COMPLETED AS NECESSARY THEREAFTER:

Purpose of Change	Released By Signature/Print Name	Received By Signature/Print Name	Date
Provide Specimen for Testing	DONOR		

## STEP 5 -- (SEE BELOW -- TO BE COMPLETED BY EMPLOYEE)

## STEP 6 -- BEFORE COMPLETING THIS STEP HAVE EMPLOYEE COMPLETE STEP 5 BELOW. To be completed by person collecting specimen:

Collector's Name \_\_\_\_\_ Date of Collection \_\_\_\_\_  
 Print (First, M.I., Last)  
 Collection Site \_\_\_\_\_ ( ) \_\_\_\_\_  
 Facility Name and Location Telephone

Remarks concerning collection: \_\_\_\_\_

I certify that the specimen identified on this form is the specimen presented to me by the employee providing the certification below, that I have certified that it bears the same identification number as that set forth above, and that it has been collected, labeled and sealed as required by the instructions provided.

\_\_\_\_\_  
 Signature of collector

## STEP 7 -- TO BE COMPLETED BY THE LABORATORY: Accession No. \_\_\_\_\_

I certify that the specimen identified by this accession number is the same specimen that bears the identification number set forth above, that the specimen has been examined upon receipt, handled and analyzed in accordance with applicable Federal requirements, and that the results attached are for that specimen.

\_\_\_\_\_  
 Printed Name

\_\_\_\_\_  
 Signature

\_\_\_\_\_  
 Date

Copy No. 1: Original

## URINE CUSTODY AND CONTROL FORM

## STEP 1 -- TO BE COMPLETED BY EMPLOYEE/APPLICANT

Employee I.D. # \_\_\_\_\_ [PRE-PRINTED SPECIMEN I.D. #] Employer Name: \_\_\_\_\_  
 Social Security No. \_\_\_\_\_  
 or Employee No. \_\_\_\_\_

## STEP 2 -- TO BE COMPLETED BY EMPLOYER REPRESENTATIVE/OR COLLECTOR Reason for Test (Check One)

☐ Pre-employment ☐ Post Accident ☐ Random ☐ Periodic Medical  
☐ Other (Specify) \_\_\_\_\_

STEP 3 -- COLLECTOR MUST NOTE THAT TEMPERATURE OF SPECIMEN HAS BEEN READ. RECORD IF NOT WITHIN THE RANGE OF  
 32.5 - 37.7C/ 90.5 - 99.8 F: \_\_\_\_\_ ☐ WITHIN RANGE

## STEP 4 -- TO BE INITIATED BY THE PERSON COLLECTING SPECIMEN AND COMPLETED AS NECESSARY THEREAFTER:

Purpose of Change	Released By Signature/Print Name	Received By Signature/Print Name	Date
Provide Specimen for Testing	DONOR		

## STEP 5 -- (SEE BELOW -- TO BE COMPLETED BY EMPLOYEE)

## STEP 6 -- BEFORE COMPLETING THIS STEP HAVE EMPLOYEE COMPLETE STEP 5 BELOW. To be completed by person collecting specimen:

Collector's Name \_\_\_\_\_ Date of Collection \_\_\_\_\_  
 Print (First, M.I., Last)  
 Collection Site \_\_\_\_\_ ( ) \_\_\_\_\_  
 Facility Name and Location Telephone

Remarks concerning collection: \_\_\_\_\_

I certify that the specimen identified on this form is the specimen presented to me by the employee providing the certification below, that I have certified that it bears the same identification number as that set forth above, and that it has been collected, labeled and sealed as required by the instructions provided.

\_\_\_\_\_  
 Signature of collector

## STEP 7 -- TO BE COMPLETED BY THE LABORATORY: Accession No. \_\_\_\_\_

I certify that the specimen identified by this accession number is the same specimen that bears the identification number set forth above, that the specimen has been examined upon receipt, handled and analyzed in accordance with applicable Federal requirements, and that the results attached are for that specimen.

\_\_\_\_\_  
 Printed Name Signature Date

## STEP 5 -- TO BE COMPLETED BY EMPLOYEE OR APPLICANT PROVIDING SPECIMEN:

Name \_\_\_\_\_ Duty Location \_\_\_\_\_  
 Last/First/M.I.

Job Title: \_\_\_\_\_ Date of Birth: \_\_\_\_\_

If you wish to have prescription or over-the-counter medications that you may have taken or been administered within the past 30 days considered as your test results are reviewed, you may list them here or provide that information separately to your employers' Medical Review Officer:

I certify that the urine specimen identified on this form is my own; that it is fresh and has not been adulterated in any manner; and that the identification information provided on this form and on the collection bottle is correct. I consent to the submission of this specimen to the certified laboratory designated by my employer, to the analysis of the specimen for controlled substances as provided by Federal requirements, and to the release of test results from that analysis to the Medical Review Officer designated by my employer.

\_\_\_\_\_  
 Signature Date

Copy No. 2: Medical Review Officer

## URINE CUSTODY AND CONTROL FORM

STEP 1 -- TO BE COMPLETED BY EMPLOYEE/APPLICANT

Employee I.D. # \_\_\_\_\_ [PRE-PRINTED SPECIMEN I.D. #] Employer Name: \_\_\_\_\_  
 Social Security No. \_\_\_\_\_  
 or Employee No. \_\_\_\_\_

STEP 2 -- TO BE COMPLETED BY EMPLOYER REPRESENTATIVE/OR COLLECTOR Reason for Test (Check One)

☐ Pre-employment ☐ Post Accident ☐ Random ☐ Periodic Medical  
☐ Other (Specify) \_\_\_\_\_

STEP 3 -- COLLECTOR MUST NOTE THAT TEMPERATURE OF SPECIMEN HAS BEEN READ. RECORD IF NOT WITHIN THE RANGE OF  
 32.5 - 37.7C/ 90.5 - 99.8 F: \_\_\_\_\_ ☐ WITHIN RANGE

STEP 4 -- TO BE INITIATED BY THE PERSON COLLECTING SPECIMEN AND COMPLETED AS NECESSARY THEREAFTER:

Purpose of Change	Released By Signature/Print Name	Received By Signature/Print Name	Date
Provide Specimen for Testing	DONOR		

STEP 5 -- (SEE BELOW -- TO BE COMPLETED BY EMPLOYEE)

STEP 6 -- BEFORE COMPLETING THIS STEP HAVE EMPLOYEE COMPLETE STEP 5 BELOW. To be completed by person collecting specimen:

Collector's Name \_\_\_\_\_ Date of Collection \_\_\_\_\_  
 Print (First, M.I., Last)

Collection Site \_\_\_\_\_ ( ) \_\_\_\_\_  
 Facility Name and Location Telephone

Remarks concerning collection: \_\_\_\_\_

I certify that the specimen identified on this form is the specimen presented to me by the employee providing the certification below, that I have certified that it bears the same identification number as that set forth above, and that it has been collected, labeled and sealed as required by the instructions provided.

Signature of collector \_\_\_\_\_

STEP 7 -- TO BE COMPLETED BY THE LABORATORY: Accession No. \_\_\_\_\_

I certify that the specimen identified by this accession number is the same specimen that bears the identification number set forth above, that the specimen has been examined upon receipt, handled and analyzed in accordance with applicable Federal requirements, and that the results attached are for that specimen.

Printed Name \_\_\_\_\_

Signature \_\_\_\_\_

Date \_\_\_\_\_

STEP 8 -- TO BE COMPLETED BY EMPLOYEE OR APPLICANT PROVIDING SPECIMEN:

Name \_\_\_\_\_ Duty Location \_\_\_\_\_  
 Last/First/M.I.

Job Title: \_\_\_\_\_ Date of Birth \_\_\_\_\_

If you wish to have prescription or over-the-counter medications that you may have taken or been administered within the past 30 days considered as your test results are reviewed, you may list them here or provide that information separately to your employers' Medical Review Officer:

I certify that the urine specimen identified on this form is my own; that it is fresh and has not been adulterated in any manner; and that the identification information provided on this form and on the collection bottle is correct. I consent to the submission of this specimen to the certified laboratory designated by my employer, to the analysis of the specimen for controlled substances as provided by Federal requirements, and to the release of test results from that analysis to the Medical Review Officer designated by my employer.

Signature \_\_\_\_\_

Date \_\_\_\_\_

Copy No. 3: Employee

## URINE CUSTODY AND CONTROL FORM

## STEP 1 -- TO BE COMPLETED BY EMPLOYEE/APPLICANT

Employee I.D. # \_\_\_\_\_ [PRE-PRINTED SPECIMEN I.D. #] Employer Name: \_\_\_\_\_  
 Social Security No. \_\_\_\_\_  
 or Employee No. \_\_\_\_\_

## STEP 2 -- TO BE COMPLETED BY EMPLOYER REPRESENTATIVE/OR COLLECTOR Reason for Test (Check One)

☐ Pre-employment ☐ Post Accident ☐ Random ☐ Periodic Medical  
☐ Other(Specify) \_\_\_\_\_

STEP 3 -- COLLECTOR MUST NOTE THAT TEMPERATURE OF SPECIMEN HAS BEEN READ. RECORD IF NOT WITHIN THE RANGE OF  
 32.5 - 37.7C/ 90.5 - 99.8 F: \_\_\_\_\_ ☐ WITHIN RANGE

## STEP 4 -- TO BE INITIATED BY THE PERSON COLLECTING SPECIMEN AND COMPLETED AS NECESSARY THEREAFTER:

Purpose of Change	Released By Signature/Print Name	Received By Signature/Print Name	Date
Provide Specimen for Testing	DONOR		

## STEP 5 -- (SEE BELOW -- TO BE COMPLETED BY EMPLOYEE)

## STEP 6 -- BEFORE COMPLETING THIS STEP HAVE EMPLOYEE COMPLETE STEP 5 BELOW. To be completed by person collecting specimen:

Collector's Name \_\_\_\_\_ Date of Collection \_\_\_\_\_  
 Print (First, M.I., Last)

Collection Site \_\_\_\_\_ ( ) \_\_\_\_\_  
 Facility Name and Location Telephone

Remarks concerning collection: \_\_\_\_\_

I certify that the specimen identified on this form is the specimen presented to me by the employee providing the certification below, that I have certified that it bears the same identification number as that set forth above, and that it has been collected, labeled and sealed as required by the instructions provided.

\_\_\_\_\_  
 Signature of collector

## STEP 7 -- TO BE COMPLETED BY THE LABORATORY: Accession No. \_\_\_\_\_

I certify that the specimen identified by this accession number is the same specimen that bears the identification number set forth above, that the specimen has been examined upon receipt, handled and analyzed in accordance with applicable Federal requirements, and that the results attached are for that specimen.

\_\_\_\_\_  
 Printed Name Signature Date

## STEP 5 -- TO BE COMPLETED BY EMPLOYEE OR APPLICANT PROVIDING SPECIMEN:

Name \_\_\_\_\_ Duty Location \_\_\_\_\_  
 Last/First/M.I.



I certify that the urine specimen identified on this form is my own; that it is fresh and has not been adulterated in any manner; and that the identification information provided on this form and on the collection bottle is correct. I consent to the submission of this specimen to the certified laboratory designated by my employer, to the analysis of the specimen for controlled substances as provided by Federal requirements, and to the release of test results from that analysis to the Medical Review Officer designated by my employer.

\_\_\_\_\_  
 Signature Date

Copy No. 4: Collector

## URINE CUSTODY AND CONTROL FORM

## STEP 1 -- TO BE COMPLETED BY EMPLOYEE/APPLICANT

Employee I.D. # \_\_\_\_\_ [PRE-PRINTED SPECIMEN I.D. #] Employer Name: \_\_\_\_\_  
 Social Security No.  
 or Employee No.

## STEP 2 -- TO BE COMPLETED BY EMPLOYER REPRESENTATIVE/OR COLLECTOR Reason for Test (Check One)

☐ Pre-employment ☐ Post Accident ☐ Random ☐ Periodic Medical  
☐ Other (Specify) \_\_\_\_\_

STEP 3 -- COLLECTOR MUST NOTE THAT TEMPERATURE OF SPECIMEN HAS BEEN READ. RECORD IF NOT WITHIN THE RANGE OF 32.5 - 37.7C/ 90.5 - 99.8 F: ☐ WITHIN RANGE

## STEP 4 -- TO BE INITIATED BY THE PERSON COLLECTING SPECIMEN AND COMPLETED AS NECESSARY THEREAFTER:

Purpose of Change	Released By Signature/Print Name	Received By Signature/Print Name	Date
Provide Specimen for Testing	DONOR		

## STEP 5 -- (SEE BELOW -- TO BE COMPLETED BY EMPLOYEE)

## STEP 6 -- BEFORE COMPLETING THIS STEP HAVE EMPLOYEE COMPLETE STEP 5 BELOW. To be completed by person collecting specimen:

Collector's Name \_\_\_\_\_ Date of Collection \_\_\_\_\_  
 Print (First, M.I., Last)

Collection Site \_\_\_\_\_ ( ) \_\_\_\_\_  
 Facility Name and Location Telephone

Remarks concerning collection: \_\_\_\_\_

I certify that the specimen identified on this form is the specimen presented to me by the employee providing the certification below, that I have certified that it bears the same identification number as that set forth above, and that it has been collected, labeled and sealed as required by the instructions provided.

\_\_\_\_\_  
 Signature of collector

## STEP 7 -- TO BE COMPLETED BY THE LABORATORY: Accession No. \_\_\_\_\_

I certify that the specimen identified by this accession number is the same specimen that bears the identification number set forth above, that the specimen has been examined upon receipt, handled and analyzed in accordance with applicable Federal requirements, and that the results attached are for that specimen.

\_\_\_\_\_  
 Printed Name

\_\_\_\_\_  
 Signature

\_\_\_\_\_  
 Date

## STEP 5 -- TO BE COMPLETED BY EMPLOYEE OR APPLICANT PROVIDING SPECIMEN:

Name \_\_\_\_\_ Duty Location \_\_\_\_\_  
 Last/First/M.I.

Job Title: \_\_\_\_\_ Date of Birth \_\_\_\_\_

I certify that the urine specimen identified on this form is my own; that it is fresh and has not been adulterated in any manner; and that the identification information provided on this form and on the collection bottle is correct. I consent to the submission of this specimen to the certified laboratory designated by my employer, to the analysis of the specimen for controlled substances as provided by Federal requirements, and to the release of test results from that analysis to the Medical Review Officer designated by my employer.

\_\_\_\_\_  
 Signature

\_\_\_\_\_  
 Date

Copy No. 5: Employer

[FR Doc. 88-26611 Filed 11-15-88; 3:48 pm]

BILLING CODE 4910-62-C

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# **Federal Register**

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**Monday**  
**November 21, 1988**

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## **Part III**

### **Department of Transportation**

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**Federal Aviation Administration**

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**14 CFR Part 61 et al.**

**Anti-Drug Program for Personnel  
Engaged in Specified Aviation Activities;  
Final Rule**

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Parts 61, 63, 65, 121, and 135

[Docket No. 25148; Amdt. Nos. 61-81, 63-25, 65-32, 121-201 and 135-28]

RIN 2120-AC33

# Anti-Drug Program for Personnel Engaged in Specified Aviation Activities

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** This final rule sets forth regulations to require domestic and supplemental air carriers, commercial operators of large aircraft, air taxi and commuter operators, certain commercial operators, certain contractors to these operators, and air traffic control facilities not operated by the FAA or the U.S. military to have an anti-drug program for employees who perform sensitive safety- or security-related functions. A special provision has been added to the rule that provides that the final rule does not apply to any person where compliance with the final rule would violate the domestic law or policy of another country. Testing under the rule will be conducted by an employer prior to employment, periodically, randomly, after an accident, based on reasonable cause, and after an employee returns to duty to perform a sensitive safety- or security-related function for an employer. The final rule also will require that an employer provide EAP education and training services to employees and supervisors. The rule is necessary to prohibit an employee from performing a sensitive safety- or security-related function for an employer while that employee has a prohibited drug in his or her system or if that employee has used drugs as evidenced by a drug test showing the presence of drugs or drug metabolites. The rule is intended to ensure a drug-free aviation workforce and to eliminate drug use and abuse in commercial aviation.

**EFFECTIVE DATE:** This final rule is effective on December 21, 1988.

**FOR FURTHER INFORMATION CONTACT:** Dr. Robert S. Bartanowicz, Acting Deputy Director, Office of Rulemaking (ARM-1), Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267-9679.

## SUPPLEMENTARY INFORMATION:

## Availability of Final Rule

Any person may obtain a copy of this final rule by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attn: Public Inquiry Center (APA-230), 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267-3484. Requests must include the amendment number identified in this final rule. Persons interested in being placed on a mailing list for future rulemaking actions should request a copy of Advisory Circular 11-2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

## Background

On December 4, 1986, the Federal Aviation Administration (FAA) issued an advance notice of proposed rulemaking (ANPRM) (51 FR 44432; December 9, 1986) entitled "Control of Drug and Alcohol Use for Personnel Engaged in Commercial and General Aviation Activities." The ANPRM invited comment from the public on drug and alcohol abuse by personnel in the aviation industry and the options available to the FAA for regulatory or other action in the interest of aviation safety. The FAA received over 650 written comments in response to the issues raised in the ANPRM.

On March 3, 1988, the FAA issued a notice of proposed rulemaking (NPRM) (53 FR 8368; March 14, 1988) entitled "Anti-Drug Program for Personnel Engaged in Specified Aviation Activities." The NPRM set forth an analysis of the comments received on the ANPRM and proposed regulations for public comment. The FAA received over 260 written comments on the proposals contained in the NPRM.

The FAA also held a series of public hearings on the regulations proposed in the NPRM. These hearings were held on June 2, 1988, in Washington, DC; June 7, 1988, in Denver, Colorado; and June 9, 1988, in San Francisco, California. Each of the hearings was recorded by a court reporter. The transcript of each hearing and any statements or other material, submitted to the hearing panel during the hearings, have been placed in the public docket. This material also has been reviewed in the development of the final rule.

**Current Rules.** The FAA's comprehensive anti-drug program is one action in a long history of actions to combat the use of drugs and alcohol in the aviation industry. The focus of the majority of these actions has been on commercial aviation personnel, particularly the cockpit and cabin crew.

For example, pilots, flight attendants, flight engineers, and flight navigators may not act as a crewmember of a civil aircraft within eight hours after drinking an alcoholic beverage; while under the influence of alcohol; with 0.04 percent, or more, alcohol in their blood; or while using any drug that affects their faculties in any way contrary to safety. Also, crewmembers may be tested in the context of receiving medical care immediately after an accident. When there is a reasonable basis to suspect that one of these individuals has violated any of the above restrictions, these crewmembers must furnish, to the FAA, the results of any test taken within four hours of acting, or attempting to act, as a crewmember that indicates the presence of alcohol or any such drug in the person's system. Moreover, pilots, flight attendants, flight engineers, and flight navigators are required to submit to a test to indicate the percentage of alcohol in the blood when requested by a law enforcement officer who suspects that a crewmember may have violated a State or local law governing the operation of an aircraft while under the influence, or impaired by, drugs or alcohol.

The FAA may deny an application for a certificate or rating for up to one year, or may suspend or revoke an existing certificate or rating, in the case of any pilot, flight engineer, or flight navigator who has been convicted of violating a Federal or State law relating to drug trafficking or possession; who has violated the proscriptions described above; who has refused to furnish the results of any test that would indicate the presence of alcohol or drugs taken within four hours of acting, or attempting to act, as a crewmember; or who has refused to submit to an alcohol test requested by a law enforcement officer investigating violations of State or local laws. The FAA also may deny an application for a certificate or rating for up to one year, or may suspend or revoke an existing certificate or rating, in the case of any air traffic control tower operator, aircraft dispatcher, mechanic, repairman, or parachute rigger who has been convicted of a violation of a Federal or State law relating to drug trafficking or possession.

The Aviation Drug-Trafficking Control Act of 1984, which added language to sections 602 and 609 of the Federal Aviation Act of 1958, mandates that the FAA take certain actions regarding airmen involved in drug trafficking activities. The Administrator is required to revoke the airman certificate of any airman who has been convicted of violating any Federal or State law

relating to a controlled substance, other than simple possession, if an aircraft was used in, or was used to facilitate, the commission of the offense and the person served as an airman, or was onboard the aircraft, in connection with the commission of the offense. The Administrator has no discretion to review the conviction for the substantive offense. Under the 1984 legislation, the Administrator was prohibited from reissuing a certificate to that airman for up to five years but could reissue a certificate after an absolute minimum of one year, in certain extremely limited circumstances, if revocation was excessive and contrary to the public interest. As part of the Federal Aviation Administration Drug Enforcement Assistance Act of 1988, Congress amended sections 602 and 609 of the FAA Act, among other amendments to the Act, in October 1988. The statutory language now provides that the Administrator shall not issue an airman certificate to any person whose certificate has been revoked for aviation drug trafficking activities unless the airman is acquitted of the offense, a conviction upon which revocation is based is reversed on appeal, or the Administrator determines that issuance of an airman certificate will facilitate law enforcement efforts after a request from a Federal or State law enforcement official. The final rule requiring a comprehensive anti-drug program for employees in commercial aviation is consistent with these previous actions taken by the FAA.

The FAA's commitment to a drug-free workforce also applies to its own employees. The Department of Transportation began random drug testing of DOT employees in safety- and security-sensitive functions in September 1987. The Secretary's goal is to establish and maintain a drug-free workplace as intended by Executive Order 12564 and as directed by Presidential memorandum dated October 4, 1986. It is the opinion of the Department of Transportation that random drug testing is the most effective means of determining the presence of drugs or drug metabolites that may adversely affect an employee's performance of safety- or security-sensitive job functions. Pursuant to the Department's program, an employee of the Department will be removed from Federal service under several circumstances: refusal to enter or to successfully complete a drug rehabilitation or abatement program; repeat usage of drugs; refusal to provide a urine specimen for drug testing; adulteration or substitution of a urine

specimen; on-duty use of illegal drugs; or a determination that a DOT employee has engaged in illegal drug trafficking.

In order to ensure that aviation safety is not compromised by a failure to detect drug users in the aviation industry, the FAA believes that it is appropriate and necessary to establish a comprehensive anti-drug program at this time.

*Existing Industry Programs.* As part of their comments to the ANPRM and the NPRM, many employers note that they have implemented drug testing programs or employee rehabilitation programs. For example, although their drug testing programs were not specifically described, Martin Aviation implemented a drug testing program in February 1987 and Suburban Airlines has required preemployment drug testing of flight crew applicants for over a year. Federal Express Corporation currently conducts preemployment testing of all applicants and "reasonable suspicion testing" of all employees.

Tramco, Inc. is a certificated repair station employing over 600 individuals and repairing over 100 aircraft per year. Tramco instituted a drug testing and counseling program "several years ago" and believes that the program yields substantial benefits to both employees and employers. Tramco tests all applicants for jobs and conducts tests based on probable cause. Tramco's tests based on probable cause are triggered by reports of employee drug use, employee attendance patterns that may suggest a drug problem, accidents, and observation by supervisors. A Tramco employee who tests positive for drugs is suspended for a minimum of one week and may not return to work until a drug test shows no evidence of drug use. Tramco estimates that, consistent with general statistics, 20 percent of its workforce has had some involvement with controlled substances. As of the time of its comment to the NPRM, Tramco identified 10 percent of its employees as individuals who had used drugs.

Rocky Mountain Helicopters, Inc. implemented a drug testing program for its employees in July 1986. Rocky Mountain Helicopters tests all pilots, mechanics managers, and others who can affect aviation safety using preemployment, random, probable cause, and postaccident testing. Rocky Mountain Helicopters does not pay an employee's rehabilitation costs but will consider rehiring any employee who completes an approved rehabilitation program. Petroleum Helicopters, Inc. began a preemployment and periodic testing program in 1982 and supports

mandatory drug testing. Petroleum Helicopters denies employment to any applicant, and discharges any employee, who tests positive in a drug test. Petroleum Helicopters does not concur with the proposal to provide a rehabilitation opportunity to employees on the basis that an employer should not accept the risk of repeated illegal drug use among maintenance or flight personnel.

The FAA believes that the comprehensive anti-drug program, promulgated by this final rule, is not a novel concept. In light of the FAA's long history of regulatory action in the area of drug use in aviation and the significant number of industry drug testing programs currently implemented by aviation employers, the FAA believes that the agency is justified in requiring the commercial aviation industry to implement similar comprehensive anti-drug programs.

## Discussion of Comments

### *General Overview of the Major Issues*

The FAA received 261 comments in response to the NPRM. The FAA considered all timely-filed comments submitted in response to the NPRM and the testimony of 20 individuals who presented statements at the three public hearings held by the FAA. During the public hearings, the Secretary of Transportation, James H. Burnley, requested information from several individuals who presented statements at the hearings. The comment period for the NPRM closed on June 13, 1988. In order to accommodate the individuals who submitted supplemental information pursuant to the Secretary's request, the FAA also considered comments that were submitted as late as July 1, 1988.

There were several major themes presented by the commenters. Many commenters focus on the lack of evidence of significant drug use or drug abuse in the aviation industry. The commenters particularly stress this point with respect to the cockpit crew based on age, income, managerial supervision, close working relationships with peers, periodic medical exams to determine fitness for duty, and professionalism of the crew. Based on the lack of evidence, these commenters conclude that establishment of a drug testing program is unwarranted and unconstitutional. Regardless of the amount of evidence, the majority of commenters agree with the FAA's assessment that drug use and substance abuse have no place in the aviation environment. Some commenters note

that the FAA's anti-drug stance is commendable, but the true issue is the type of program that evolves from that stance. Many commenters support the FAA's efforts to develop a comprehensive anti-drug program that would achieve a drug-free commercial aviation workforce and agree that a program to achieve a drug-free aviation environment is beneficial.

There is substantial, although not universal, support for a drug testing program using state-of-the-art urine testing. The gas chromatography/mass spectrometry (GC/MS) method, approved by the Department of Health and Human Services (DHHS), is recognized by the commenters as the most accurate method of analysis for the presence of drugs or drug metabolites in urine if rigorous collection and analysis procedures, such as those contained in the DHHA mandatory guidelines, are followed. (As discussed in detail elsewhere in this preamble, the Department of Transportation is publishing "Procedures for Transportation Workplace Drug Testing Programs" which are adopted in this final rule in lieu of the DHHS guidelines. These DOT-wide procedures closely resemble the DHHS guidelines and are used because the DHHS guidelines are not drafted for application by entities other than Federal agencies.) While some concerns were raised about the testing procedures, these concerns generally involve drug testing programs and procedures in the early 1980s that did not embody the critical safeguards of a properly-administered testing program.

Certain types of testing proposed in the NPRM receive significant support by the commenters. These types of testing include preemployment testing and postaccident testing. Periodic testing and testing based on reasonable cause received substantial support from the commenters. Some support for testing based on reasonable cause is predicated on traditional constitutional standards that apply to a search of the person.

There is significant and strongly-held opposition to random testing. However, the FAA's drug testing program, including random testing as a critical element, is supported by some commenters. The objections to random testing are based on legal or constitutional issues, privacy issues, and the invasive nature of random testing based on personal grounds, cost issues, and the absence of a demonstrated need for a comprehensive testing program assuming a low level of drug use in the industry.

Of those commenters who address the issue, there is agreement that the

complexity, cost, and operational impact burdens of the rule would be significantly greater on small entities in the aviation industry. Finally, the commenters express significantly different opinions in the area of employee assistance programs (EAP). The primary differences surround the issues of the circumstances under which an employee is offered an opportunity for rehabilitation and the entity or individual who is responsible for payment of rehabilitation costs. Several major air carriers have already addressed this issue through insurance coverage or by labor-management agreement. However, even some of these organizations, although supportive of EAPs, oppose a broad, Federally-mandated EAP requirement. Labor organizations clearly support expansive EAP opportunities and services. Small entities oppose EAP requirements on many grounds, including cost and possible negative coworker attitudes exhibited toward rehabilitated employees.

The commenters differ regarding the method of achieving a drug-free aviation workforce and the manner in which the FAA would be involved in any program. The primary differences arise regarding the type and scope of testing used to identify sensitive safety- or security-related personnel who use drugs and the choices offered to those individuals who are identified as drug users.

*Labor Unions and Organizations Representing Employees.* In general, unions or organizations representing employees in aviation oppose the comprehensive mandatory drug testing proposed in the NPRM. Labor unions and employee organizations favor EAP and broad rehabilitation rights for all employees. These organizations oppose random drug testing but, with some qualifications, these organizations see a role for preemployment testing, postaccident testing, testing based on reasonable cause, and testing during and after rehabilitation to monitor an individual's progress.

The International Association of Machinists and Aerospace Workers (IAM) opposes any industry-wide drug and alcohol testing until hard evidence of an industry drug problem that jeopardizes aviation safety is substantiated and documented. The Independent Union of Flight Attendants (IUFA) opposes all forms of mandatory drug testing of employees. The Independent Federation of Flight Attendants (IFFA) objects generally to drug testing as unwarranted governmental intervention into labor-management relations but would support preemployment screening and

postaccident testing if reasonable cause for such testing can be objectively illustrated. IFFA objects specifically to random testing in any form as unconstitutional and contrary to labor law. IFFA believes that the focus of any drug testing program should be limited to impairment on the job and states that no currently available testing procedure can determine drug impairment on the job. The Association of Flight Attendants (AFA) believes that drug testing of flight attendants is not warranted. However, AFA and the Association of Professional Flight Attendants (APFA) support preemployment testing of applicants seeking jobs in the industry if that testing is not used to discriminate against applicants on the basis of disabilities unrelated to drug use. AFA also would not oppose postaccident testing of pilots or probable cause drug testing of employees who are under the influence of drugs if these samples were collected by an FAA inspector. APFA opposes random testing, postaccident testing absent individualized suspicion, and testing based on reasonable cause as proposed. The Flight Engineers' International Association (FEIA) opposes all testing except in the case where probable cause exists to believe that an employee is impaired by drugs; in order to protect employees from harassment, FEIA states that any determination to test an employee based on probable cause for impairment should be reviewed by a neutral party. The Teamsters Union could support preemployment screening; testing based on reasonable suspicion to believe that an employee's actual or current impairment has, or is, affecting job performance or workplace safety; periodic testing to maintain medical certification; and testing after an accident or a "near miss" if there is a reasonable basis to suspect that human error may have been a causal factor.

The Air Line Pilots Association (ALPA), representing 41,000 pilots employed by 44 large and small airlines, is firmly opposed to all forms of drug and alcohol abuse by airline personnel. ALPA primarily is opposed to random and periodic testing based on their belief that these tests are offensive, ineffectual, unjustified, and unconstitutional. ALPA believes that if there is drug use among commercial pilots, the incidence of drug use would be less than 0.5 percent. On this basis, ALPA asserts that widescale random testing of the relatively small aviation population will result in a significant number of false-positive test results. ALPA does not oppose testing prior to

employment, testing after an accident, testing in circumstances where there are reasonable grounds to suspect drug use, and testing to monitor rehabilitation.

ALPA believes that the approach to the drug abuse problem articulated in the NPRM is inappropriate. ALPA instead urges the FAA to consider an approach similar to the Human Intervention Motivation Study (HIMS) program developed to identify and treat alcoholism among pilots. The key elements of the HIMS program are education, peer involvement, intervention, confrontation, and rehabilitation. Although the HIMS program has focused on treatment of pilots who demonstrate a problem with alcohol, ALPA sponsored a HIMS drug abuse training program in November 1987 which the FAA attended.

Labor and employee organizations also strongly support limitations on an employer's ability to exclude any employee from an opportunity for rehabilitation and limitations on an employer's ability to discharge an employee. Most organizations, including IUPA, IFFA, AFA, and APFA, strongly support regulations that would require an employer to establish and participate in comprehensive, nonpunitive EAP services established by collective bargaining or negotiation and available to all employees. ALPA agrees that any regulations should clearly recognize that unions have collective bargaining rights under Federal labor laws; ALPA suggests that any anti-drug regulations promulgated by the FAA should ensure that the regulatory requirements do not interfere or override the union's collective bargaining rights. FELA supports EAP services, mandatory for each carrier and paid for by the carrier, for rehabilitation of all employees regardless of the circumstances that precipitated a drug test. IAM suggests that FAA regulations should be guidelines, applicable only to carriers who have a documented substance abuse problem affecting aviation safety, that stress education, prevention, rehabilitation, and protection of an employee's privacy.

**Employers and Organizations Representing Employers.** Most employers support mandatory drug testing of employees and limitations on an employee's opportunity for rehabilitation. Part 121 and Part 135 certificate holders do not express the same opinions regarding the proposals in the NPRM. The general views held by Part 121 certificate holders are characterized by the comments submitted by the Air Transport Association of America (ATA). ATA

supports the FAA's comprehensive drug testing program and favors an opportunity for rehabilitation only for those employees who volunteer for rehabilitation. In the area of EAP services, Part 121 certificate holders generally favor flexibility and latitude for an employer to design a company EAP. American Airlines, however, favors industry-wide standard EAP requirements.

Most Part 135 certificate holders and small aviation businesses object to the drug testing requirements proposed in the NPRM. The Regional Airline Association (RAA), which represents many Part 135 certificate holders, opposes random testing; RAA also suggests that the random selection rate be set at a rate less than the maximum 125 percent rate proposed in the NPRM if the FAA mandates a random testing requirement. The Primary objection of Part 135 certificate holders and small businesses is to the proposed requirement to offer an opportunity for rehabilitation to an employee. These organizations oppose mandated rehabilitation because of the economic burden that would be imposed on a small operator. The National Air Transport Association (NATA) suggests, in its June 2, 1988 testimony, that Part 135 certificate holders employing 100 or fewer covered employees should be exempted from all requirements of the proposed anti-drug program.

Grace Flying Service, Inc., a Part 135 certificate holder conducting single-engine air taxi services, flight instruction, and aerial application services, opposes drug testing of employees. Grace Flying Service strenuously objects to any drug tests, whether scheduled or random, and would be reluctant to test its employees even if testing is mandated by the FAA.

The National Business Aircraft Association (NBAA) concurs with the FAA's anti-drug program with certain reservations. NBAA primarily is concerned about the constitutionality of random drug testing and the FAA's reliance on laboratory testing results that may be unreliable in detecting drugs or drug metabolites proposed to be analyzed in the NPRM.

**Individual Commenters.** The FAA received 170 comments from individuals. The majority of these individuals are pilots employed by major airlines and self-employed pilots who would be subject to the requirements of the proposed rule. The FAA also received comments from general aviation pilots and individuals who are not employed in the commercial aviation industry. The vast majority of the individual

commenters oppose the drug testing requirements of the proposed rule based on constitutional objections, failure of the FAA to demonstrate a drug problem in the aviation community, and perceived inaccuracies of drug testing collection and analysis. A minority of individual commenters generally support the FAA's anti-drug proposals and primarily support the testing requirements. These individuals are private citizens or consumers who base their support on the need to ensure that aviation personnel are drug free, particularly on the job. The strongest individual support is expressed by letters from the family and friends of a passenger who was killed in the crash of Continental Air Express Flight 2286 near Durango, Colorado. The comments from the family and friends of the deceased passenger urge the FAA to do everything within its statutory authority to prevent a similar tragedy in the future.

#### *Specific Issues*

**Discussion of the constitutional issues regarding random and periodic drug testing.** A number of commenters have questioned the constitutionality of drug testing programs for aviation personnel. Although the state of the case law is still evolving in rapid fashion and no definitive Supreme Court resolution of many relevant and complex issues has been achieved, the FAA feels confident that testing required under this rule will pass constitutional scrutiny. The FAA recognizes that there are legitimate and significant constitutional concerns surrounding drug testing in general and random drug testing as a specific component of drug testing. The FAA acknowledges the current widescale litigation and apparent disparate judicial opinions on drug testing programs.

**FAA Response.** The principles of the Fourth Amendment to the U.S. Constitution are paramount in scrutinizing the fundamental legality of many drug testing programs. As a threshold legal matter, the Fourth Amendment applies to "searches" conducted or mandated by the government and protects individuals against "unreasonable searches and seizures." Action of a private party does not constitute State (or Federal) action unless there exists a close nexus between the state and the action in question. *Jackson v. Metropolitan Edison*, 419 U.S. 345 (1974); *Moose Lodge No. 107 v. Irvis*, 407 U.S. 163 (1972).

Assuming that the drug testing programs called for under the final rule do implicate the government, a second

issue then arises concerning whether urine tests under these programs are "searches" within the meaning of the Fourth Amendment. Although most courts to address the issue to date have ruled that toxicological testing of employees for the purpose of determining fitness for duty is a search within the meaning of the Fourth Amendment, the issue is not entirely settled. See *Wyman v. James*, 400 U.S. 309, 317-338 (1971) (government welfare caseworker's "home visit" as a precondition for assistance payments is not a Fourth Amendment search). See also, *Lovvorn v. City of Chattanooga*, 846 F.2d 1539, 1553-1554 (6th Cir. 1988) (Guy, J., dissenting), panel decision vacated and rehearing en banc ordered, (August 3, 1988); *National Treasury Employees Union v. von Raab*, 808 F.2d 1057, 1060, 1062 (5th Cir. 1987) (Higginbotham, J., concurring). Cf. *Mack v. United States, F.B.I.*, 814 F.2d 120, 125 n.2 (2nd Cir. 1987).

Also assuming, *arguendo*, that urine tests of aviation personnel for illegal drugs are "searches" within the meaning of the Fourth Amendment, it is clear that while searches ordinarily must be conducted pursuant to a warrant issued on probable cause grounds, such a requirement is not always necessary. *Almeida-Sanchez v. United States*, 413 U.S. 266, 277 (1973) (Powell, J., concurring). Where, for example, " \* \* \* the burden of obtaining a warrant is likely to frustrate the governmental purpose behind the search \* \* \* " [*Camera v. Municipal Court*, 387 U.S. 523, 533 (1967)], the Supreme Court has routinely held that a warrant is not required by the Fourth Amendment. See e.g., *Griffin v. Wisconsin*, 107 S.Ct. 3164, 3167 (1987); *New Jersey v. T.L.O.*, 469 U.S. 325, 340 (1985). The Supreme Court has likewise found that the probable cause standard is inappropriate where it would defeat the purpose that the search is designed to achieve. See e.g., *New Jersey v. T.L.O.*, 469 U.S. at 340-342; *O'Connor v. Ortega*, 107 S.Ct. 1492, 1501-1502 (1987) (plurality opinion) (upholding the search of a public employee's office for work-related noninvestigatory reasons on less than probable cause grounds); *United States v. Martinez-Fuerte*, 428 U.S. 543, 560-561 (1976) (footnotes omitted) [while " \* \* \* some quantum of individualized suspicion is usually a prerequisite to constitutional search or seizure, \* \* \* the Fourth Amendment imposes no irreducible requirement of such suspicion"].

Rather, "[t]he fundamental command of the Fourth Amendment is that searches and seizures be reasonable

\* \* \*." *New Jersey v. T.L.O.*, 469 U.S. at 340. In determining the reasonableness of a search, the Supreme Court has repeatedly stressed the importance of the facts particular to the search while acknowledging that the test of reasonableness " \* \* \* is not capable of precise definition or mechanical application." *Bell v. Wolfish*, 441 U.S. 520, 559 (1979). In analyzing a drug testing program, " \* \* \* what is reasonable depends on the context within which a search takes place." *New Jersey v. T.L.O.*, 469 U.S. at 337.

In scrutinizing whether particular searches comport with the Fourth Amendment, courts have adopted a balancing test. In general, to support a claim that a search of an individual or the individual's property is reasonable, the government must demonstrate that, on balance, the public's legitimate interest in conducting the search outweighs the individual's legitimate expectation of privacy. See e.g., *United States v. Montoya de Hernandez*, 473 U.S. 531, 537 (1985); *United States v. Villamonte-Marquez*, 462 U.S. 579, 588 (1983); *Delaware v. Prouse*, 440 U.S. 648, 654 (1979). Thus, the courts must " \* \* \* consider the scope of the particular intrusion, the manner in which it is conducted, the justification for initiating it, and the place in which it is conducted." *Bell v. Wolfish*, 441 U.S. at 559.

Viewed in this light, it is beyond dispute that the public has an overriding interest in assuring that sensitive safety- and security-related aviation personnel perform their duties free of illegal drugs. The drug problem in society in general and evidence of drug use in the aviation industry in particular are documented elsewhere in the preamble of this final rule. The impairing effects of illegal drugs and the substantial risks to public safety posed by aviation employees who use illegal drugs underlies the compelling governmental interests in promulgating this final rule.

In contrast, the drug testing requirements of the final rule involve a minimal invasion of privacy. As the Supreme Court has indicated, where searches are undertaken in situations where individualized suspicion is lacking, other safeguards must be relied upon to ensure that the discretion of the party conducting the search is properly defined and the scope of the search is limited. See *Delaware v. Prouse*, 440 U.S. at 654-655 (footnote omitted); *New York v. Burger*, 107 S.Ct. 2636, 2648 (1987). The drug testing requirements of the final rule place significant constraints on an employer's discretion in conducting drug testing. For example,

the requirement for random drug testing calls for selection of an employee to be tested in a scientifically-acceptable manner, such as use of a computer-based random number generator. Requirements for testing based on reasonable cause or postaccident testing also are severely circumscribed in order to limit an employer's discretion in administering such tests to employees. Also, the FAA will review the actual employer anti-drug programs, required to be submitted to the agency in accordance with provisions of the final rule, to ensure that discretion is in fact limited in the administration of drug tests under these programs. Cf. *National Treasury Employees Union v. Reagan*, No. 86-4058, slip op. at 14 (E.D.La. April 29, 1988) (holding that the constitutionality of Executive Order requiring Federal agencies to establish drug testing programs for Federal employees was not ripe for review since each agency had not implemented a finalized, particular plan).

The actual testing procedures that each employer is required to implement under this final rule also are tailored narrowly to respect an employee's reasonable expectation of privacy. The DOT procedures governing collection of urine samples, which are based on the DHHS guidelines, are carefully designed to preserve privacy while protecting the integrity of the sample. The final rule contains a number of important employee safeguards, including privacy during collection under the majority of circumstances, stringent laboratory safeguards, and provisions for challenging results. Other employee drug testing programs incorporating the collection and testing procedures of the DHHS guidelines have been upheld against constitutional attack. The DOT procedures so closely resemble the DHHS guidelines in all pertinent respects that the Department of Transportation is confident that these procedures also will be upheld. See *American Federation of Government Employees v. Dole*, 670 F.Supp. 45 (D.D.C. 1987), appeal docketed, No. 87-5417 (D.C.Cir. Dec. 11, 1987) (upholding the constitutionality of the Department of Transportation program for random drug testing of safety- and security-sensitive agency employees); *National Association of Air Traffic Specialists v. Dole*, 2 Ind.Emp.Rts. Cases (BNA) 68 (D.Alaska 1987) (denying a motion for a preliminary injunction against the FAA's use of urinalysis drug testing as part of an annual physical examination of the agency's air traffic specialists).

Equally significant is the fact that urine drug testing of sensitive safety-

and security-related employees is to be conducted in the "context" of the employment relationship. As the Supreme Court has pointed out, "[t]he operational realities of the workplace \*\*\* may make some employees' expectation of privacy unreasonable." *O'Connor v. Ortega*, 107 S.Ct. at 1498. This is particularly important in circumstances where the employee works in an industry in which his or her activities are subject to extensive regulation. Thus, persons who work in such "closely regulated" industries have a "reduced expectation of privacy" [*New York v. Burger*, 107 S.Ct. at 2646] and, "in effect consent[] to the restrictions placed upon them" [*Almeida-Sanchez v. United States*, 413 U.S. at 271]. For these very reasons, two Federal courts of appeals have upheld urinalysis testing, in the absence of particularized suspicion, in industries where pervasive regulation has reduced an employee's expectation of privacy. See *Rushton v. Nebraska Public Power Dist.*, 844 F.2d 562, 566 (8th Cir. 1988) (nuclear plant operators); *Shoemaker v. Handel*, 795 F.2d 1136, 1142 (3rd Cir.), cert. denied, 479 U.S. 988 (1986) (jockeys); *Policemen's Benevolent Ass'n., Local 318 v. Township of Washington*, 850 F.2d 133 (3rd Cir. 1988) (police officers).

It is beyond dispute that aviation has always been subject to pervasive regulation by the government and by employers themselves. As one Federal district court has noted:

[t]he rationale of the Third Circuit upholding drug urinalysis for jockeys in order to protect the integrity of horse racing is even more compelling when the public need for air safety is considered. If horse racing is recognized as a closely or pervasively regulated activity, then aviation activities and the aviation industry are as much or possibly more closely regulated.

Indeed, the creation of a federal agency charged with the responsibility for ensuring safe air travel reflects the public interest in air safety. \*\*\* [T]he public perception of air safety not only is critical to the airline industry but to all who fly. \*\*\* [C]lose and pervasive regulation of aviation related activities is well established and \*\*\* air safety relates to serious risk or hazards which require close and constant attention. *National Association of Air Traffic Control Specialists v. Dole*, 2 Ind. Emp. Rts. Cases (BNA) at 78.

The FAA recognizes that a number of Federal and State courts have rejected government-mandated drug testing program of Fourth Amendment grounds. However, even courts striking drug testing programs have recognized that drug testing is appropriate in other contexts. See e.g., *Lovvorn v. City of Chattanooga*, 846 F.2d at 1553-1554

(Martin, J.) ("When determining, then, whether a mandatory drug search is 'reasonable,' we believe that, as the costs to society of an impaired employee increase, the requisite level of suspicion that a drug problem exists decreases."); *Policemen's Benevolent Ass'n., Local 318 v. Township of Washington*, 872 F.Supp. 779, 792 (D.N.J. 1987), rev'd, 850 F.2d 133 (3rd Cir. 1988) ("[T]he need to prevent a major airline disaster presents a far more compelling rationale than those presented by the municipality in support of testing its police officers."); *American Federation of Government Employees v. Meese*, No. C-88-1419-SAW (N.D.Cal. June 16, 1988) (issuing a preliminary injunction against a Bureau of Prison plan to test randomly all agency employees but nonetheless noting that "[t]here are cases in which compulsory drug testing may be justified in the interest of public safety or security." Memorandum opinion at 2).

The FAA also is aware of the recent Ninth Circuit decision holding unconstitutional regulations promulgated by the Federal Railroad Administration—mandating blood and urine tests of railroad employees who are involved in certain train accidents and fatal incidents and authorizing breath and urine tests after certain accidents, incidents, and rule violations—because the rules do not require a showing of "particularized suspicion" drug or alcohol impairment prior to testing. *Railway Labor Executive's Association v. Burnley*, 839 F.2d 575 (9th Cir.), cert. granted, 108 S.Ct. 2033 (1988). The Ninth Circuit based its views, in part, on the proposition that "the vast bulk of [railroad] safety regulation is directed at owners and managers of railroads, not employees." *Id.* at 585. The U.S. government disagrees with the Ninth Circuit panel's decision, which is contrary to rulings in other Federal appellate courts. Moreover, contrary to the Ninth Circuit's views of the Federal Railroad Administration's jurisdiction over railroad employees, FAA's jurisdiction over employees in the aviation industry is clear and should not be subject to challenge on this basis.

The Supreme Court has granted the government's petition for a writ of certiorari in *Railway Labor Executives' Association v. Burnley* and has ordered that this case be argued this term "in tandem" with *National Treasury Employees Union v. von Raab*, 816 F.2d 170 (5th Cir. 1987), cert. granted, 108 S.Ct. 1072 (1988) (upholding drug testing of applicants for critical safety or security sensitive positions in the U.S. Customs Service). Decisions in these cases may not be forthcoming until the

spring of 1989. However, in the absence of Supreme Court guidance, the FAA remains convinced that the need for drug testing by urinalysis in the aviation industry to determine fitness for duty of sensitive safety- or security-related employees and, thereby, to ensure public safety clearly outweighs the privacy interest of individuals in this class.

While not totally free from doubt, it is the opinion of the Department of Transportation that the FAA's anti-drug program, and similar regimens proposed by other administrations within the Department, will be determined to be constitutional. The critical need for properly-administered drug testing to ensure that employees in the transportation industry do not have drugs or drug metabolites in their system while performing sensitive safety- and security-related functions outweighs the reduced privacy interest of these employees.

**Lack of Evidence of a Drug Problem in the Aviation Industry.** Nearly every commenter who opposes drug testing in general, and random testing in particular, and even commenters who support the comprehensive drug testing proposals, raise the issue of lack of evidence of a drug problem in commercial aviation. On this basis, the commenters assert that the FAA can not justify the comprehensive proposals contained in the NPRM. ALPA, the Aircraft Owners and Pilots Association, (AOPA), and the organizations representing flight attendants maintain that the industry should police itself in the area of drug use and abuse.

**FAA Response.** The FAA made no attempt to obscure the lack of widespread evidence of drug use or abuse among commercial aviation personnel. However, after publication of the NPRM in the *Federal Register* on March 14, 1988, federal investigators released preliminary data showing that the captain of Continental Air Express Flight 2286, which crashed in Durango, Colorado on January 19, 1988, may have been impaired by drugs while operating the aircraft. A preliminary report of the National Transportation Safety Board (NTSB) indicates that toxicological test results show that the captain of Flight 2286 had cocaine and a cocaine metabolite in his system at the time of the crash. Seven passengers and the pilot and copilot died in the accident.

In 1983, the NTSB issued an Aircraft Accident Report (NTSB/AAR-84/11) on the crash of Central Airlines Flight 27 in Newark, New Jersey, on March 30, 1983. The NTSB determined that the probable cause of the crash of the Gates Learjet

nonscheduled, cargo-carrying aircraft included "impairment of the flight crew's judgment, decisionmaking, and flying abilities by a combination of physiological and psychological factors." The NTSB did not conclude that drug-impaired performance was the sole cause of the crash. However, the report does state that test results indicate that the captain had used marijuana and the copilot had used, or been exposed to, marijuana within the 24 hours preceding the crash. Also, toxicological tests indicate that the copilot's urine showed evidence of contra-indicated use of an antihistamine drug.

Additional evidence of illegal drug use by individuals employed in the airline industry appeared in the fall of 1986, when a series of articles in the Pittsburgh Press, based on interviews with emergency room staffs at area hospitals, highlighted 23 cases of airline flight crew drug abuse. Twenty of those cases involved cocaine overdoses, two were heroin reactions, and one dealt with valium and alcohol. Twelve cockpit crewmembers and eleven cabin crewmembers were among those treated by Pittsburgh area hospitals for drug use. Personnel at those hospitals also indicated that they had treated numerous cases of drug abuse among non-flight employees, such as mechanics. The Pittsburgh Press also surveyed 17 drug treatment clinics across the country and found that more than 69 pilots had been treated for cocaine addiction. A subsequent FBI investigation of drug use in the Pittsburgh area produced evidence that a number of airline employees, including cockpit, cabin, and ground crewmembers, had used cocaine, marijuana, and other illegal drugs, sometimes on duty or shortly before reporting for duty.

The NPRM also included comments by a Part 121 and Part 135 certificate holder that implemented an unannounced drug testing program applicable to its employees. This company reported that 2.5 percent of its 180 pilots and 4 percent of its 240 mechanics tested positive for a trace, or more, of illegal drug in their system. Data from the airline industry regarding preemployment screening of applicants for various positions indicate that the number of positive drug tests ranges from 4.2 percent to 20 percent with results as high as 25 percent to 30 percent in some geographical locations.

Although this data does not show an overwhelming drug problem in commercial aviation, it does show concrete evidence of drug use in the

commercial aviation sector. The FAA recognizes that commercial aviation personnel operate in a professional and highly-regulated environment. However, pursuant to the FAA's statutory mandate to ensure aviation safety, the FAA also must acknowledge that commercial aviation personnel are not immune to, nor insulated from, drug use or abuse that may affect safety-critical job performance. The FAA believes that any drug use in commercial aviation warrants preventive and proactive intervention by the FAA to ensure aviation safety. The FAA believes that this view is not inconsistent with the increasing awareness of several aviation employers who currently have, as disclosed in their comments, basic drug testing and employee rehabilitation programs for their employees.

Although not a universally-expressed opinion among the commenters, ATA "fully embrace[s] the philosophy, expressed in the NPRM, that individuals who wish to work in aviation activities that involve the safety of passengers, co-workers, and others must not use illicit drugs, even while off-duty." Several commenters, including RAA, note that to the extent any drug use is occurring in the aviation industry, it is a "safety issue and it is well within the purview of the FAA to develop a comprehensive, nationally applicable set of regulations." The Equal Employment Advisory Council (EEAC) believes that the workplace is an appropriate environment to intervene in the process of individual substance abuse. EEAC also believes that the FAA has correctly concluded that the purpose of drug testing is not to determine that an employee is impaired by drugs at the time of testing. Instead, testing is used to enable an employer rationally to determine if an employee has used drugs and to conclude reasonably that there is a possibility of future impairment based on subsequent use.

*Comments that the Proposed Rules are Politically-Motivated.* The FAA received many comments that state that the comprehensive anti-drug program proposed by the FAA is based solely on political perceptions and goals. The commenters stress that DOT and the FAA have surrendered to the public hysteria over drug use and unfavorable press reports of drug use in the aviation industry.

*FAA Response.* Because this issue is raised so frequently by the commenters, the FAA chooses to address these comments although they are beyond the scope of the rulemaking. The war against drugs is one of this Administration's top priorities. Also,

Congress has enacted a substantial amount of legislation to address the use, distribution, importation, and interdiction of drugs in the United States and is considering enactment of additional legislation. Moreover, a significant number of public opinion polls indicate that the American public is deeply concerned about the effect of drug use by individuals in critical safety occupations, including aviation. The fact that the Administration, Congress, and the public are concerned about drug use is noteworthy. However, the FAA is issuing the comprehensive anti-drug program in this final rule because it is consistent with the FAA's statutory duty to promulgate minimum standards to ensure and promote aviation safety.

*DHHS Guidelines.* The FAA received numerous comments, including comments from drug testing laboratories and companies supplying drug testing equipment, on the guidelines for drug testing promulgated by the Department of Health and Human Services (DHHS). Many of the commenters state that the certification requirements for drug testing laboratories are too rigid because the DHHS guidelines require laboratories to have the capability to do both initial and confirmation testing at the same laboratory site. The Director of the Santa Maria Public Airport District and Psychomedics Corporation, a commenter at the San Francisco public hearing, suggest that the FAA use analysis of hair, in lieu of urinalysis testing, to test for drugs on the basis that hair analysis may be more accurate and more reliable. Psychomedics Corporation proposes that analysis of hair samples would produce more complete results because hair contains a "longitudinal" history of drug use that could reveal drug use in excess of 90 days before analysis. This commenter also notes that the two-step process of immunoassay and GC/MS analysis would still be used; the only change would be the material that was analyzed. Federal Express strongly opposes implementation of the DHHS guidelines because they are overly-burdensome on carriers with operations in multiple locations.

Some commenters also state that a split sample should be obtained from each individual in order to ensure the accuracy of the analysis. Several commenters raise the issue that specimens may be used by an employer to test for physiological states, including epilepsy and pregnancy, to discriminate against applicants and employees. A few commenters consider the requirement of "monitored" specimen collection, whether by listening to or

directly observing an individual, to be embarrassing and intrusive.

The AMA opposes the proposal to require employers to comply with the DHHS guidelines. The AMA states that these requirements would result in an undue hardship on aviation medical examiners who must comply with chain-of-custody procedures designed to ensure the integrity of the specimen.

The NTSB strongly concurs in the requirement that drug testing laboratories that analyze specimens pursuant to the drug testing program must meet the scientific and technical DHHS guidelines and must be certified by the Department of Health and Human Services. Insofar as the DHHS guidelines are inconsistent with other NTSB comments, the NTSB recommends that the FAA revise the guidelines for the industry drug testing program. ATA agrees that only DHHS-approved labs should be used for analyzing specimens but that the DHHS guidelines should be tailored to accommodate the particular needs of the aviation industry.

The SYVA Company and Drug Screening Systems, Inc. submitted comments to the FAA on the DHHS guidelines. Both companies are involved in the manufacture and supply of drug screening systems and equipment. These companies urge caution in the FAA's proposal to adopt the DHHS guidelines based on the restrictive and possibly burdensome nature of the requirements on employers required to conduct drug tests pursuant to the rule. These companies address several issues, including batch requirements, on-site collection, threshold drug levels, and development of new testing procedures not permitted under the current DHHS guidelines.

IFFA feels strongly that the Enzyme Multiplied Immunoassay Technique (EMIT) test should not be used as part of laboratory analysis of specimens because the test detects only the presence of a drug metabolite of the active drug and it often results in false-positive results, false-negative results, or misidentified results.

ALPA generally supports the proposal to make the DHHS guidelines applicable to collection and analysis of specimens. However, ALPA believes that the FAA's regulation should contain additional employee safeguards. First, the regulation should require split samples during collection. Second, the regulation should require that threshold drug levels determined by a confirmation test be consistent with the initial test to account for quantitative discrepancies in test results that are not attributable to deterioration of the sample. Third, ALPA suggests that an employee should be

able to present the results of an independent test result to an MRO during review of test results to determine the validity of a positive test result. Fourth, the regulation should allow labor and management, through collective bargaining, to inspect laboratories and to perform quality control and administrative functions related to any anti-drug program.

Labor unions, including TWU and the Teamsters Union, advocate development and implementation of separate or additional guidelines to safeguard the selection and performance of laboratories analyzing specimens for drugs or drug metabolites.

EEAC believes that the DHHS guidelines are a valuable contribution to the goal of establishing procedural norms in collection and testing of specimens. However, EEAC believes that employers should establish individual procedures to ensure the integrity of a sample and its analysis. EEAC emphasizes that it is inappropriate for the FAA to impose such detailed requirements on private employers.

**FAA Response.** In the NPRM, the FAA proposed that all collection of specimens and drug testing take place in accordance with the "Mandatory Guidelines for Federal Workplace Drug Testing Programs" published by the Department of Health and Human Services (53 FR 11970; April 11, 1988). The DHHS guidelines describe the collection and testing procedures applicable to all drug testing in the Federal government, and they include safeguards for the accuracy and privacy of collection and testing.

The Department of Transportation has determined that certain modifications of the DHHS guidelines are appropriate in the context of this and other DOT-operating administration drug-free workplace regulations. The result will be the DOT "Procedures for Transportation Workplace Drug Testing Programs," which will be codified at 49 CFR Part 40. These DOT procedures are intended to preserve, to the greatest extent practicable, the important safeguards provided by the DHHS guidelines.

Some of the modifications to the DHHS guidelines will be editorial in nature (e.g., references to responsibilities of "agencies" are changed to references to "employers"). Other modifications are intended to take into account differences in the situations of Federal agencies and DOT-regulated industries. For example, in testing at remote sites, DOT-regulated industries may find it necessary to conduct some kinds of testing in medical facilities or

through the use of mobile units, rather than the more permanent collection sites contemplated by the DHHS guidelines. It may not be practicable for regulated employers to maintain on-site permanent logbooks. Consequently, the DOT procedures would permit alternative collection and recordkeeping procedures in these circumstances.

The Office of the Secretary in the Department of Transportation will publish elsewhere in today's **Federal Register** an interim final rule with request for comments entitled, "Procedures for Transportation Workplace Drug Testing Programs," that will codify the Department of Health and Human Services guidelines for drug testing at 49 CFR Part 40. This new part will set forth requirements for such things as specimen collection procedures, laboratory procedures, and quality assurance and certification procedures. The rule will provide guidance on how this rule shall be implemented.

During the comment period on the FAA's NPRM, and those rules proposed by other DOT operating administrations, comments were received concerning the DHHS guidelines. These comments are noted in this preamble and also will be transferred to the Department of Transportation to be incorporated in the docket for the Office of the Secretary (OST) interim final rule creating 49 CFR Part 40. OST will respond to those comments, as well as comments received during the comment period for Part 40, in its notice following the end of that comment period.

The FAA proposed only urine testing in the proposals contained in the NPRM. The suggestion of drug testing using analysis of hair specimens raises an issue within the expertise of the Department of Health and Human Services. Thus, at this time, DOT and the FAA do not intend to deviate from urinalysis as the technique for determining the presence of drugs or drug metabolites in an employee's system.

The FAA acknowledges the AMA comments regarding the inability of all aviation medical examiners to comply with the collection and chain-of-custody procedures contained in the DHHS guidelines due to the lack of appropriate facilities for collection. The FAA does not agree with the AMA that the requirements are overwhelming or overly-burdensome. Although the AMA was not specific regarding its objection to the collection and chain-of-custody procedures, DOT has included provisions in the DOT procedures to address some of the difficulties

associated with collection and chain-of-custody procedures that may not have been appropriate for private entities. However, the FAA and DOT believe that strict collection and chain-of-custody procedures are critical to ensure the integrity and identity of a specimen provided by an employee. Thus, DOT has retained these protections in its modification of the DHHS guidelines. Moreover, only those aviation medical examiners who choose to provide this service to commercial aviation personnel during a physical examination are required to conform to the minimum procedures contained in the DOT procedures.

Consistent with the suggestion of the NTSB and other commenters, the Department of Transportation will modify the DHHS guidelines to tailor the provisions for application by private entities. The DOT procedures will not modify the basic, technological aspects of the rule (e.g., DHHS certification of laboratories, testing methodologies, collection procedures, and chain-of-custody procedures). Any arguably substantive changes from the DHHS guidelines will be included only to reduce practical and administrative burdens on private entities. These changes will be discussed in an ancillary document published by the Department of Transportation in the *Federal Register*. DOT and the FAA believe that the DOT procedures will provide adequate and appropriate procedures for collection and testing of samples. Although the FAA anticipates that the DOT procedures will prove to be an effective and efficient method of collection and testing, experience under the testing program or a change in the circumstances or needs of the industry may warrant further regulatory revisions in the future.

**Accuracy of Drug Test Results.** Many commenters base their opposition to drug testing on the perceived inaccuracy of analysis and test results. The commenters include the issues of false-positive test results, passive inhalation of illicit drugs, misidentification of licit drugs, and ingestion of food substances, including poppy seeds, resulting in a positive drug test result.

**FAA Response.** The FAA is aware of these expressed concerns because each of these issues surfaced in the early 1980s with the first series of drug testing programs introduced in the military and the private sector. In the early years of drug testing and analysis, laboratory security and analytical procedures had not reached today's level of sophistication. False-positive test results occur primarily in analysis of a

specimen during an initial screening test, although contemporary screening tests, such as immunoassay tests, have become extremely accurate and approach 99 percent accuracy levels. Despite its increased accuracy, the initial screening test remains a less expensive test used only to yield a preliminary indication of the possible presence of drugs or drug metabolites. In order to ensure the integrity and accuracy of any test result, each positive initial screening test result must be confirmed using GC/MS analysis or another confirmatory procedure that may be subsequently approved by DHHS and incorporated into the DOT procedures. The GC/MS confirmation test is an extremely accurate and sophisticated test and is virtually error-free when used in compliance with the DHHS guidelines. The DOT "Procedures for Transportation Workplace Drug Testing Programs" (49 CFR Part 40), will be essentially identical to the "Mandatory Guidelines for Federal Workplace Drug Testing Programs" published by the Department of Health and Human Services on April 11, 1988.

Employers must comply with the DOT procedures when conducting a testing program pursuant to the final rule. Like the DHHS guidelines, the DOT procedures will provide a system of checks and balances during collection and analysis of specimens. This system ensures the integrity and accuracy of the tests using appropriate scientific methods and rigid chain-of-custody procedures. An employer may only use a laboratory that complies with the DOT procedures. Also, an employer may only use a laboratory that has been certified by DHHS to process and analyze specimens required by the FAA rule. The DOT procedures regarding testing methodologies and technical matters will be identical to the DHHS guidelines. Thus, employers will be able to use any DHHS-certified laboratory since the laboratories will not necessarily be required to use different analytical techniques and testing methodologies for different entities conducting testing. The Department of Transportation expects that sufficient laboratories will have been certified for drug analysis by the Department of Health and Human Services by early 1989. However, the FAA will extend the compliance dates contained in this final rule if DHHS has not certified a sufficient number of laboratories to efficiently and accurately process and analyze specimens pursuant to the requirements of this final rule.

Since the mid-1980s, laboratories have become increasingly sophisticated in

their analytical methods and chain-of-custody procedures. Many laboratories have compiled extensive records demonstrating scientific accuracy and protection of individual specimens. For example, CompuChem Laboratories, a major drug testing laboratory, has analyzed over 500,000 urine samples, conducting discrete testing for nine different drugs which resulted in nearly five million distinct analyses of these specimens, since 1980. CompuChem also has analyzed approximately 750,000 urine samples for the presence of two different drugs, resulting in nearly 1.5 million analyses of these specimens, pursuant to its contract with the military. None of the over six million analyses performed for DOT, the military, and other private and public entities has resulted in a false-positive test result.

In late 1987, a CompuChem clerical worker incorrectly labeled two samples that belonged to DOT employees. Within hours after the test results were questioned by the medical review officer, CompuChem and the medical review officer had identified and corrected the error. CompuChem was not satisfied with its prompt resolution of the error. As stated in its comment to the NPRM, CompuChem has instituted an additional system of review, by CompuChem personnel and computer checks, to ensure that "this one in a million error will not reoccur."

Another drug testing firm, PharmChem Laboratories, has conducted over eight million nonmilitary drug tests nationwide. In its statement to the FAA during the public hearing held in San Francisco on June 9, 1988, PharmChem notes that several courts have determined that the GC/MS confirmation test is "virtually 100 percent accurate, assuming that proper chain-of-custody procedures are followed."

The FAA does not believe that the issue of "passive inhalation" of marijuana smoke will prove to be a significant issue leading to false-positive test results. First, PharmChem's statement indicates that the DHHS threshold levels that would result in a positive drug test result for the presence of marijuana or marijuana metabolites (to be incorporated completely and without change in the DOT procedures) are set at a level sufficiently high to preclude the possibility of a positive test result based on passive inhalation of marijuana smoke. Second, studies conducted to simulate the conditions that result in passive inhalation have been conducted in artificially-devised and extremely confining areas that were

poorly ventilated. Also, in order to obtain a positive test result, testing was conducted immediately after this prolonged and intensive exposure to the marijuana smoke. Based on the FAA's knowledge of these studies, the FAA has concluded that it is highly unlikely that the identical circumstances would be encountered or accurately reproduced outside a laboratory.

Finally, the FAA believes that the safeguards that will be provided in the DOT procedures and by the medical review officer (MRO) review process, which are essentially identical to the DHHS guidelines, will preclude misidentification of food substances or licit drugs that might produce a false-positive test result. The DOT procedures will provide an individual with an opportunity to report any legal or prescription drugs that he or she may be taking at the time of collection of the specimen. The MRO's broad authority to interpret each confirmed positive test result, to evaluate an employee based on the MRO's knowledge of drug abuse disorders, and to verify that a confirmed positive test result is accurate should preclude misidentification of food substances or licit drugs taken in accordance with a valid prescription. In summary, the FAA believes that the two-step testing process, coupled with the DOT procedures, provides a process by which an individual is protected from erroneous false-positive drug test results.

**Preemployment Testing.** Most organizations and individuals do not object to the concept of preemployment testing. AOPA supports preemployment testing at the discretion of the employer. Operators who hire pilots or crewmembers pursuant to short-term contracts believe that a preemployment test is burdensome if required each time a pilot is rehired pursuant to a new contract. These entities suggest that preemployment tests be given only at the time of training or placement on a bid list for contracts.

Suburban Airlines has required preemployment testing of all flight crew applicants for over a year. Suburban supports 100 percent preemployment testing of the aviation employees proposed in the NPRM. The Director of the Santa Maria Public Airport District also supports preemployment testing and suggests that preemployment testing be implemented immediately.

The Soaring Society of America (SSA) believes that small business employers should have the option of requiring preemployment drug testing as a condition of employment. SSA feels that preemployment testing should be optional because applicants can

circumvent detection in a preemployment drug test merely by abstaining from drug use for a short period of time before the preemployment test.

**FAA Response.** The FAA believes that preemployment testing is a necessary component of an effective anti-drug program. Pursuant to the rule, a preemployment drug test is required only when an applicant has been selected for employment in a sensitive safety- or security-related position with the employer. The preemployment testing provision does not require an employer to test each applicant for a sensitive safety- or security-related position. The rule simply states that an employer may not hire an applicant to perform sensitive safety- or security-related functions unless the applicant has passed a drug test. Therefore, the employer need only test an applicant before actually hiring the applicant for a sensitive safety- or security-related position.

The FAA has revised the proposed rules in ways which should ease the burden on operators who frequently rehire employees pursuant to short-term contracts. The FAA believes that the central issue regarding the frequency of preemployment testing is the continuity of an employee's involvement in an employer's drug testing program. An employer is required to conduct a preemployment test only the first time that an employee is hired pursuant to a contract with that employer so long as the individual remains in the employer's program, even during periods between contracts. The individual, thus, would be subject continuously to drug testing. In addition, so long as an employee is subject to an FAA-approved anti-drug program, another employer may use that employee to perform sensitive safety- or security-related functions. Thus, an individual who participates through a consortium would be able to provide services on a contract basis to multiple employers without having to submit to subsequent preemployment tests or to participate in another employer's drug testing program. If an employee has not been continuously subject to an FAA-approved anti-drug program, an employer would be required to conduct a preemployment drug test.

In the FAA's opinion, it would be permissible for an employer to allow a contract employee to continue in the employer's anti-drug program after termination of a contract. Particularly in the case of an employer who hires employees pursuant to a series of short-term contracts, both the employer and the employee benefit if the employee is continuously subject to a drug testing

program. The employer could "rehire" the employee at any time but would not be required to give the employee another preemployment drug test. In addition, the employee could perform sensitive safety- or security-related functions for another employer on a temporary basis but would not be required to participate in another employer's anti-drug program or to submit to another preemployment drug test. To the extent that the employee is not covered by an FAA-approved anti-drug program, an employer would be required to conduct a preemployment drug test before the employee could be hired by a subsequent employer or rehired by a previous employer.

**Periodic Testing.** AOPA believes that periodic drug testing should not be part of an employer's drug testing program but should only be conducted based on the reasoned judgment of an aviation medical examiner. RAA supports periodic testing during medical certification at least once each calendar year. RAA believes that the employee should bear the cost of the periodic test. Federal Express does not oppose periodic testing but believes that it should be unrelated to the FAA medical examination.

The AMA opposes periodic drug tests as part of a routine medical examination because compliance with collection and chain-of-custody procedures, such as those contained in the DOT procedures and the DHHS guidelines, would be an undue burden on aviation medical examiners.

ATA stated that its association is not convinced that periodic testing effectively deters illicit drug use because of the relative ease with which this test can be circumvented by abstinence. SSA generally does not endorse periodic testing because an employee can avoid detection by relatively short-lived abstinence before any announced periodic test.

**FAA Response.** The FAA agrees with the commenters that announced periodic testing can be circumvented by an employee's abstinence from drug use. However, periodic testing does enable an employer to identify those employees who are so heavily-dependent on drugs that they are unable to abstain from drug use for even a short period of time prior to a periodic test.

The FAA has modified the periodic testing requirement of the regulation. Under the proposed regulation, an employee who holds a medical certificate would have been required to submit a specimen for drug testing as part of each medical examination required pursuant to Part 67. The revised

section makes it clear that an individual is required to submit a specimen for drug testing during the first medical examination of the employee during the calendar year after implementation of the anti-drug program. Therefore, pilots who hold Class I medical certificates, who are required to have periodic medical examinations at 6-month intervals, must be tested only once during one of the medical examinations of the year pursuant to the anti-drug program.

The revised section also states that an employer may discontinue periodic testing after the first year of program implementation when the employer has implemented its random testing program according to the implementation schedule and, therefore, is conducting a significant number of random tests. The periodic testing requirement will ensure that all current employees who hold medical certificates will be tested once during the first year of implementation of an employer's anti-drug program; most of the employees who hold medical certificates also will be subject to random selection for testing during part of the first year of implementation. The majority of random testing programs will be operational after the first year of implementation and periodic testing, which is less effective than random testing, will no longer be a necessary component of an employer's anti-drug program. The FAA anticipates that these revisions will provide maximum drug detection capability and ease the transition to a full random testing program. The FAA considers the revision to be appropriate to relieve some of the significant economic and administrative burdens noted by the commenters who believe that periodic testing is an ineffective and ineffective drug deterrent.

**Random Testing.** Most individual commenters oppose random testing for a variety of reasons. Among these reasons is the lack of evidence of drug use or abuse in aviation to warrant random testing, invasion of individual privacy, and violation of constitutionally-protected rights.

AOPA opposes random testing primarily on the basis of the unsettled constitutional issues surrounding random testing and the burden imposed by this testing method on law abiding citizens. AOPA suggests that the FAA delay promulgation of a final rule until the issues raised by random testing are substantially resolved by the Supreme Court in *Railway Labor Executives' Association v. Burnley* and *National Treasury Employees Union v. von Raab* (cited previously). AOPA states that, by

awaiting any Supreme Court decision, the FAA could ensure that the final rule is in conformity with guidance enunciated in the Supreme Court's opinion in *Burnley* and *von Raab*. One commenter submitted comments individually, as national litigation counsel for AOPA, and on behalf of the California Aviation Council and the Orange County Aviation Association. This commenter states that the NPRM is an unconstitutional invasion of privacy and a violation of an individual's procedural due process rights. The commenter believes that the NPRM should be withdrawn to await the Supreme Court's impending decisions.

The AMA supported random testing only as part of a comprehensive rehabilitation program. The AMA believes that random testing is not cost effective, is unnecessarily intrusive, and, without confirmation testing, random screening tests are inaccurate.

In addition to soliciting comments on the general concept of random testing, the FAA solicited comments on an appropriate random testing rate of up to 125 percent. Several small business entities, including TEMSCO Helicopters, Inc., Henson Airlines, and Tramco, Inc., oppose the random testing requirement based on the financial and administrative burdens associated with a 125 percent testing rate, transportation of employees to the collection site, and replacement of personnel during testing. TEMSCO Helicopters suggests that a random testing rate of 10 percent will enable the industry to determine if there is a drug problem in aviation without overburdening the industry. RAA also believes that a 125 percent random testing rate is overreaching and unwarranted; however, if the FAA proceeds with a random testing provision, RAA suggests that a 50 percent random testing rate is appropriate. Although Suburban Airlines strongly supports random testing, Suburban believes that a 50 percent random testing rate of the employees proposed in the NPRM would relieve the unjustifiable economic burden on a cost-benefit basis. ERA Aviation, Inc., a Part 121 and Part 135 certificate holder operating more than 12 helicopters and 12 airplanes, believes that unannounced random testing is the most effective deterrent to drug abuse. However, ERA questions a requirement to randomly test 125 percent of the employees on an annual basis. ERA believes that random testing of 25 percent to 50 percent of the affected employee groups, coupled with periodic testing, would provide a sufficient

deterrent to drug use if the penalties for positive test results were severe.

NTSB opposes the random testing requirement of the proposed rules. However, if random testing were included in the final rule, the NTSB believes that a relatively high random testing rate would be a more effective deterrent to drug use. The acting Chairman of the NTSB did not concur with the NTSB's position regarding random testing; the acting Chairman supports random testing provided that the random testing rate is sufficiently high to serve as a deterrent to drug use.

ATA, American Airlines, and Delta Airlines support the FAA's mandatory random testing provision because it would provide the maximum deterrent effect to illicit drug use. ATA supports a random testing rate of 50 percent based on a review of Department of Defense and private industry drug testing programs. American Airlines also supports the mandatory random testing provision and a 125 percent random testing rate. A consultant to American Airlines on the issue of drug abuse prevention in the workplace, who submitted an affidavit attached to comments by American Airlines, is convinced that random drug testing is "the only powerful and proven means of detecting drug use and drastically reducing drug use and thereafter preventing further drug problems from occurring." On the other hand, Federal Express states that random testing should be permitted, but not mandated, by regulation. Federal Express states that if the FAA ultimately mandates random testing, carriers should be allowed to choose a random testing rate between 15 percent to 50 percent. Federal Express also believes that carriers should be free to set different random testing rates for different groups of employees.

There was almost universal opposition to random testing by unions and organizations representing employees. ALPA, the Transport Workers Union of America (TWU), and the International Brotherhood of Teamsters (Teamsters Union) are adamantly opposed to random testing. ALPA (Council #12) concurs in ALPA's general opposition to random drug testing of professionals in the aviation industry. The Teamsters Union states that a drug testing program is a change in working conditions which, in accordance with Federal labor law, is a mandatory subject of collective bargaining.

SSA does not oppose random testing of employees. However, in order to provide a workable and effective anti-

drug program for small business, SSA suggests that entities employing 12 or fewer full-time employees be exempted from the random testing requirement. SSA defines "full-time employees" as those individuals who work for an employer at least 30 hours per week or 5 days per week and have maintained that schedule for at least 90 days.

One commenter, who spoke at the San Francisco public hearing on June 9, 1988, has been a practicing physician for 24 years and has devoted the past seven years to the exclusive practice of aviation medicine. This commenter has worked regularly with EAP representatives and has been involved with " \* \* \* hundreds of airline employees before, during and after treatment for drug and alcohol dependencies." Based on the commenter's extensive experience in drug and alcohol use by aviation employees, he observes that the present system of relying on " \* \* \* peer and supervisory identification, and a highly visible employee assistance program," and on a scheme of "preemployment, for-cause and fitness-for-duty drug testing, enables significantly impaired employees to remain in the workforce." Therefore, this commenter concludes that in order to eliminate those remaining risks, " \* \* \* there is nothing more we can do short of random testing."

**FAA Response.** While noting the constitutional issues surrounding the issue of random testing discussed previously, the FAA continues to believe that unannounced testing based on random selection is a fundamental component of an effective drug testing program. Unannounced, random testing has proven to be an effective deterrent to drug use and will provide safety benefits to the aviation community by reducing or eliminating drug use by sensitive safety- or security-related aviation personnel. Unannounced, random testing programs initiated by the military, including the Coast Guard, and private industry show declining drug use, evidenced by a decrease in the number of individuals who test positive for drugs, over the course of the drug testing program.

The FAA received many comments regarding the proposed random testing rates. Several commenters suggest a random testing rate of 125 percent because that rate would result in the most significant deterrent to drug use in the aviation industry. However, other commenters who address this issue believe that a 125 percent random testing rate would be excessive and would impose a significant economic

burden, particularly on small aviation businesses. The commenters propose a range of random testing rates starting at 10 percent annually. The majority of the commenters suggest that an annual 50 percent random testing rate for the aviation industry is appropriate. These commenters believe that the 50 percent testing rate accomplishes several goals consistent with the intent of the proposal.

In response to the commenters, the FAA has substantially revised the random testing proposal in the NPRM in order to reduce the practical and administrative burdens associated with initiating an unannounced testing program based on random selection of employees. The FAA's approach also is designed to provide a random testing rate that balances cost effectiveness and burdens on employees and employers but still results in an effective and credible deterrent to drug use.

For some employers, particularly those with a large number of employees subject to drug testing, it may be a substantial burden to move from no random drug testing of employees directly to random testing of 50 percent of the covered employees. For example, if required to have tested 50 percent of all covered employees by the end of the first year, employers might have to test at rates far above a 50 percent rate toward the end of the year, to make up for lower rates at the beginning of the year. Employers should be permitted to start the program at a lower testing rate and work up to a 50 percent rate as experience is gained and the testing procedure becomes administratively routine. The FAA does not want to create a situation which might lead to inadvertent mistakes by requiring initial unannounced testing based on random selection at too high a rate.

The final rule, therefore, provides an implementation procedure that would allow employers to phase in unannounced drug testing based on random selection of employees during the first 12 months in which tests are required to be conducted. Employers would not be required to reach an annualized rate of 50 percent until the last test collection of the first year of the program. The total number of unannounced tests based on random selection of employees during the first 12 months of the employer's testing program would have to equal at least 25 percent of the covered employee population. Also, the employer is required to space the tests reasonably throughout the year. This approach will provide a sufficient level of deterrence

to drug use and will permit the employer to phase in the 50 percent rate.

Suppose, for example, that an employer has 1000 sensitive safety- or security-related employees. At a 50 percent annual rate, the employer would be required to conduct 500 unannounced tests based on random selection during a year. Under the phased approach, however, the employer could conduct only a few drug tests at the beginning of the program and then gradually increase the number of tests until, by the end of the first year, the annualized rate of 50 percent was achieved. Thus, if the employer's drug testing plan contemplated administration of unannounced tests based on random selection on 12 occasions during the year, the employer would need to collect 42 urine specimens for analysis (500 divided by 12) on the last occasion, but could collect fewer specimens until then. Overall, the employer would have to collect at least 250 specimens for analysis during the first year. In subsequent years, the employer is required to maintain the 50 percent annualized rate for unannounced testing based on random selection of employees.

The FAA believes that the final rule provides a moderate, but substantial, level of testing based on random selection that enables an employer to increase random testing gradually during the first year of program implementation. During subsequent years of the program, the employer must maintain an annualized rate of 50 percent of the covered employees. In order to determine the appropriate number of employees that must be tested to reach the appropriate "annualized rate" for the random testing program, the employer shall refer to the number of employees subject to the rule at the beginning of a calendar year.

At this time, the FAA believes that this phased program, ultimately reaching a testing level equivalent to 50 percent of the covered employees, will provide a sufficient deterrent to drug use without imposing an undue economic or administrative burden on employers and employees subject to the requirements of the regulation. In addition, the program will produce a sufficient data base at different annualized rates and testing levels for the FAA to analyze the scope of any drug problem in the commercial aviation industry generally or within any particular sector of the commercial aviation community. Analysis of the random drug testing data submitted by an employer will allow the FAA to determine if the

random testing program should be revised in any manner.

The phased program and the final 50 percent random testing rate is consistent with the random testing program currently applicable to safety- and security-sensitive employees of the Department of Transportation. DOT's random testing program began in September 1987; the random testing rate has gradually increased and will reach an annualized rate of 50 percent by October of this year. Data from September 1987 to the present show that the current detection rate found as a result of DOT's random drug testing program is 0.83 percent; data from February 1987 to the present show that the current detection rate for FAA and DOT's periodic (e.g., scheduled) testing program is 0.012 percent.

According to the provisions of the final rule, all employers are required to randomly select a sufficient number of employees to enable the employer to conduct unannounced testing of employees who perform sensitive safety- or security-related duties for the employer at the appropriate rate during the calendar year. In order to conduct enough tests to reach the required percentage, an employer may be required to select a number of employees who perform a sensitive safety- or security-related functions for unannounced testing that is in excess of the actual number to meet the required percentage. Selection of a greater number of employees enables the employer to reach the appropriate annualized rate despite absences due to vacations and medical leave or absences due to an inability to reach a collection site resulting from travel or duty requirements.

If a consortium has been established among employers or operators, the consortium would be required to select and to test the appropriate rate of the aggregate total of employees subject to the final rule who are covered by the consortium. The testing rate of the consortium will be attributed to each employer participating in the consortium. In the FAA's opinion, the consortium's testing rate can be attributed to each participating employer, although less than the appropriate percentage of the employees of a particular employer has been tested during a calendar year, without significantly decreasing the deterrent effect of a random testing program. An employer or consortium that develops a random selection scheme involving preliminary selection criteria, such as geographical zones, must specify these schemes or variations in the employer's

anti-drug plan. The FAA realizes that these variations may provide administrative ease for an employer. However, the FAA must review these variations to ensure that the scheme does not dilute the required annualized rate required by the final rule.

The FAA received comments from small aviation businesses regarding the difficulty of testing a large number of employees on a random basis during the first year of implementation of the rule. In response to these comments, the FAA substantially revised the provisions of the proposed rule. Certain Part 135 certificate holders whose total workforce includes 11 to 50 sensitive safety- or security-related employees are given additional time to submit a random testing plan and to ensure that the appropriate percentage of the sensitive safety- and security-related employees are subject to unannounced drug testing on a random selection basis during a calendar year. The FAA encourages these employers to develop a comprehensive random testing plan as soon as possible. As discussed later, Part 135 certificate holders that employ 10 or fewer covered employees and those individuals or entities listed in § 135.1(b), who are otherwise exempt from the requirements of Part 135 but are included in the final rule because they are engaged in operations for compensation or hire, are given additional time to develop and implement an anti-drug program that includes random testing. The FAA notes that the final rule does not restrict the ability of these employers to submit a random testing program, and to implement that program, earlier than the timeframes contained in the final rule.

Some commenters address the issue of the difficulty in developing an efficient and successful random testing program. The FAA notes that the rule provides flexibility to an employer to begin the random testing program at a lower random testing rate so long as the required percentage of covered employees have been selected on a random basis and have been tested by the end of the first year after approval of the employer's anti-drug program or random testing plan. For example, an employer may test small increments of employees at the beginning of a period and may test a large percentage of employees at the end of the same period to achieve the annualized rate that is required by the final rule.

**Postaccident Testing.** AOPA supports postaccident testing if it is conducted by the NTSB. AOPA believes that postaccident testing should not be a part of an employer's drug testing program

and should not be conducted by the FAA.

The NTSB comments that the 24-hour period provided for postaccident testing is excessive. The NTSB recommends that the FAA specify a maximum period of four hours for collection of a postaccident drug test and provide an appropriate penalty for failure to collect the specimen within the 4-hour period. The NTSB believes that delays of more than four hours in sample collection impair detection of a drug and its "psychoactive component(s)" in blood samples, particularly substances such as cocaine, marijuana metabolites, some amphetamines, and phencyclidine (PCP). The NTSB also suggests that blood testing is the preferable method for postaccident testing and suggests that the FAA permit this method of testing for the presence of drugs after an accident. ATA also suggests that postaccident testing should be conducted within 4 hours after an accident and, in no case, later than 12 hours after an accident.

ATA recommended that the NTSB's definition of "incident" should be added to the postaccident testing provision to cover situations when an aircraft is empty or when personal injury or physical damage is less severe than specified in the postaccident testing provision. ATA also believes that postaccident testing should be conducted unless a supervisor determines that an employee's drug use was not a contributing factor in the accident. FEIA believes that postaccident testing is "wasteful and intrusive" unless the accident clearly is caused by the person to be tested and there is individualized probable cause to believe that the employee was impaired at the time of the accident.

SSA does not completely endorse postaccident testing based on a variety of practical considerations that SSA believes are unresolved in the regulation as proposed. However, SSA states that postaccident testing, after an NTSB-defined accident, of any employee working for a small business should be conducted as deemed feasible by the employer. SSA believes that postaccident testing should be conducted within 24 hours if the employer determines that testing is feasible and appropriate. Also, if the employer determines that testing is not feasible, the FAA may request an explanation from the employer during the routine investigation of the accident.

**FAA Response.** In the NPRM, the FAA proposed that postaccident tests be conducted within 24 hours after an accident based on the possibility that

difficulties may arise after an accident in transporting an individual to a collection site or bringing a drug testing kit to the scene of the accident. The FAA is aware that extended delays in sample collection and testing after an accident may result in deterioration or elimination of a drug or a drug metabolite from a person's system. Recognizing these difficulties and concerns, the FAA has modified the postaccident testing provision. Under the final rule, an employer must conduct postaccident testing of an employee as soon as possible after the accident but in no case later than 32 hours after the accident. Selection of this time period comports with the DOT's postaccident drug testing program for DOT employees, which provides a maximum of 8 hours to determine if an employee is required to be tested and an additional 24 hours to actually obtain a sample for testing.

The FAA strongly encourages employers to promptly determine if an employee is subject to postaccident testing, particularly in cases where there is little or no uncertainty that an employee's performance was a contributing factor in the accident. The FAA intends to vigorously enforce the regulation where there is unreasonable delay in determining whether an employee should be tested under this provision or where there is unreasonable delay in testing after the determination to test is made. Although several commenters who address the issue suggest time periods of less than 24 hours, it is the FAA's opinion that a maximum period of 32 hours is a workable and reasonable accommodation that is appropriate for the aviation industry.

The NTSB's suggestion that the FAA require an employer to conduct postaccident testing within four hours after an accident is based on the time-sensitive nature of toxicological testing of blood samples. On the other hand, urinalysis testing does not involve the extreme time-critical considerations associated with collection and testing of blood samples. In the FAA's opinion, postaccident urinalysis testing is sufficient at this time to provide an indication of an individual's drug use that may have been a causal factor in an aviation accident.

Also, the FAA proposed only urine testing in the NPRM, specifically excluding blood testing as an option, for all drug tests that would be conducted under the anti-drug program. Therefore, the FAA considers the NTSB's suggestion to be beyond the scope of the notice and the FAA has not adopted

NTSB's suggestion to permit postaccident testing by collecting a blood sample. In the aviation context, the significant proportion of serious accidents involving fatalities to crewmembers provides data with respect to drug involvement in those accidents. In the FAA's judgment, extending full toxicological testing to surviving crewmembers is not warranted at this time.

Presently, the FAA is not convinced that including the NTSB's definition of "incident" as a trigger for drug testing is warranted. As discussed below, the FAA believes that the revisions to the section providing for testing based on reasonable cause will adequately address circumstances that might qualify as "incidents." The current provisions allow sufficient, but limited, latitude to an employer to determine whether an employee should be tested following an incident or an accident not covered by the NTSB's definition of accident.

Although several commenters suggest that the FAA expand the scope of the postaccident testing provision, the FAA believes that the postaccident testing provision, limiting testing to only those employees whose performance may have been a cause of the accident, is appropriate. The FAA believes that it is inappropriate to require postaccident testing of an employee whose performance could not have been a cause of the accident merely because that employee happens to have been onboard or involved with an aircraft involved in an accident.

*Testing Based on Reasonable Cause.* The NTSB suggested that the FAA include "incidents," as defined by the NTSB's rules, as events that would trigger reasonable cause testing. RAA agrees with the requirement that two supervisors, one with training in the symptoms of drug abuse, must concur in the decision to test an employee based on reasonable suspicion of drug use. RAA believes that each carrier should determine the conditions which constitute reasonable suspicion. FEIA also believes that two supervisors, trained to detect symptoms of drug abuse, must concur in all decisions to test based on probable cause. ATA suggests that only one supervisor be required to trigger testing of an employee based on reasonable cause. In addition, ATA states that supervisors should not be required to have specialized training for the purpose of determining when reasonable cause exists to test an employee.

Tramco, Inc. believes that the proposed circumstances that would

support a decision to test based on reasonable cause are too restrictive. Tramco believes that an employee's attendance patterns, tips from coworkers, "error rates," and other indirectly observable indications should also trigger testing based on reasonable cause. Tramco currently uses these triggers in its drug testing program; Tramco believes that the FAA's criteria will not result in detection of possible drug users because it is limited to physical and observable indices of gross impairment. SSA supports "for-cause" testing, as the employer deems necessary and feasible, if testing is conducted pursuant to the DHHS guidelines.

IAM and TWU believe that the criteria that would trigger testing based on reasonable cause are ill-defined. These organizations believe that testing based on reasonable cause will be a tool for employee harassment; these organizations suggest that supervisory personnel should be trained to recognize the symptoms of drug impairment or that at least one of the supervisors making the determination to test should be someone other than the employee's immediate supervisor. The Teamsters Union and IAM believe that decisions and determinations related to testing based on reasonable cause should be documented and supported in a written report.

The Newton Psychological Centre submitted a "basic identification profile," developed to aid supervisors of the Philadelphia Electric Company in identification of employees who may not be fit for duty. The profile is used to detect early warning signs of problems based on medical or psychological problems. The profile sets forth behavioral, emotional, physical, biological, and cognitive cues related to the use of marijuana, cocaine, alcohol, barbiturates, amphetamines, and heroin, or cues related to anxiety or depression. The company's policies regarding alcohol and substance abuse, job performance warning signs, and counseling and confrontation guidelines are printed on the profile.

*FAA Response.* As stated in the FAA's response to comments submitted on the postaccident testing provision, the FAA is not including a "postincident" testing provision at this time. However, the circumstances under which a supervisor could require an employee to submit to a test based on reasonable cause have been modified in the final rule. Based on the comments submitted, particularly by employers who have existing "reasonable cause" testing programs, the FAA has expanded

the list of circumstances that might trigger testing under this provision. Evidence of repeated errors on the job, regulatory or company rule violations, or unsatisfactory time and attendance patterns, if coupled with a specific, contemporaneous event that indicates probable drug use, could provide additional, cumulative evidence to support a decision to test an employee based on reasonable cause.

As proposed in the NPRM, an employer is permitted to test a specimen provided by an employee, collected pursuant to a reasonable cause determination, for the presence of any drug or drug metabolite listed in Schedule I or Schedule II of the Controlled Substances Act. The employer may test for these drugs, as part of the employer's approved anti-drug program, if the employer has specific approval from the FAA to include these controlled substances in the employer's anti-drug program. In addition, the testing for these additional drugs must be conducted in accordance with the DOT procedures to be codified in 49 CFR Part 40.

The FAA believes that the provision requiring two supervisors, one of whom has specialized training in detecting the symptoms of drug use, to concur in the decision to test an employee based on reasonable cause is appropriate for large companies. However, the FAA has revised this section of the rule in order to address the legitimate concerns of small employers, many of whom do not have more than one supervisor employed at the company. For companies that employ 50 or fewer employees who perform a sensitive safety- or security-related function, the rule specifies that only one supervisor is required to make the determination that would trigger testing of an employee based on reasonable cause. The FAA also has clarified the annual EAP training requirements for supervisors to make it clear that supervisors who make reasonable cause determinations must have specific training that will enable them to assess and demonstrate the basis for testing based on reasonable cause.

**Testing after Return to Duty.** ATA believes that the FAA should not set regulatory standards governing postrehabilitation testing. ATA, other employer and employee organizations, and many individual commenters believe that a schedule for postrehabilitation testing should be made by management in consultation with persons involved in an employee's rehabilitation program. In order to ensure continued disassociation from

drugs, RAA supports a requirement for monthly screening, for 12 months, after an employee has completed rehabilitation.

APFA believes that a schedule for postrehabilitation testing should be determined by an employee's EAP counselor and should be limited to a reasonable period of no more than one year. AFA states that decisions regarding testing after rehabilitation should be the responsibility of the individual treatment facility used by the employee.

**FAA Response.** The FAA agrees with the commenters that suggest that unannounced testing during any rehabilitation and before an employee returns to duty should be determined by the persons involved in the employee's rehabilitation program. Decisions regarding the frequency of testing during any rehabilitation program appropriately lie with those individuals who are familiar with and involved in any employee rehabilitation program.

However, unannounced testing after an employee returns to duty is critical to ensure an employee's continued disassociation from drugs. The FAA believes that it is essential to require unannounced testing of employees who have returned to duty in a sensitive safety- or security-related position for an employer after failing a drug test given by an employer or after refusing to submit to a drug test required by the final rule. This type of testing is the most effective means of ensuring that an employee remains drug free while performing commercial aviation duties. Moreover, once an employee has returned to duty, the FAA and the employer have a substantial interest in requiring that employee to be drug free while performing sensitive safety- or security-related duties in commercial aviation. Therefore, the FAA has included a provision in the rule requiring an employer to monitor an employee who has returned to duty by providing unannounced drug testing, pursuant to a schedule determined by the MRO, for not more than 60 months after the employee has returned to duty.

The rule also provides that an employer must conduct unannounced testing of an individual who is hired to perform a sensitive safety- or security-related function after failing a drug test or after refusing to submit to a drug test for another employer and who has not previously been subject to return-to-duty testing. This section of the final rule addresses situations where an individual fails a drug test or refuses to submit to a drug test but does not return to duty for an employer. In this case,

any subsequent employer would be required to test an individual for not more than 60 months after the individual is hired to ensure that the individual is drug free. In the FAA's opinion, if an employee failed a drug test given by a previous employer but returned to duty with that employer in accordance with the requirements of this final rule, a subsequent employer would not be required to reevaluate a prior employer's return-to-duty decision. An employer would be required to test this individual prior to employment but would not be required to monitor the employee after the employee was hired. Pursuant to the final rule, the medical review officer (MRO) has the discretion to determine the appropriate level of unannounced testing for an individual or an employee. The FAA believes that it is appropriate to allow the MRO to tailor the frequency of this type of testing to adequately address differences between individuals, the level and type of drug use, and any treatment or counseling program.

The FAA notes that the MRO also is required to ensure that an employee has been tested for drugs, in accordance with the procedures in the final rule and the DOT procedures, before being hired or returning to duty. In most cases, the MRO will not be required to arrange testing for an employee because the employee will have taken a drug test as part of any employee rehabilitation program. However, the MRO must ensure that an individual or employee has been tested, in accordance with the procedures of Appendix I to Part 121 and the DOT procedures, before the MRO can make a recommendation that an individual be hired or that an employee be returned to duty after failing a drug test or after refusing to submit to a drug test. In the FAA's opinion, a preemployment drug test would suffice to satisfy this requirement of the final rule.

**Employee Assistance Programs and Rehabilitation.** The FAA sought comment in the NPRM regarding three different EAP options. These options specified the circumstances under which an employee would be given the opportunity to seek rehabilitation. Option 1 would allow all employees to seek an opportunity for rehabilitation regardless of how the employee's drug use was detected. Option 2 would allow most employees, except those employees whose drug use was detected as a result of postaccident testing or testing based on reasonable cause, to seek an opportunity for rehabilitation. Option 3 would only allow employees who volunteer to seek rehabilitation and

would exclude all employees whose drug use was detected by any other means. Under all three options, an employer would not be required to offer an opportunity for rehabilitation or to provide job security to any employee who was identified as a drug user on the job.

Employer organizations tend to support the third option proposed in the NPRM regarding rehabilitation and reemployment or job security opportunities that should be offered to employees. Part 121 certificate holders, as generally noted by ATA, support the third option. For example, Delta Airlines believes that the most effective deterrent to drug use is the threat of losing a job. On that basis, Delta states that mandatory rehabilitation and an opportunity for continued employment would diminish the effectiveness of the rule. American Airlines disagrees with ATA's position and supports the first option. Federal Express supports the third option if the FAA mandates rehabilitation. The Helicopter Association International (HAI) states that requiring an employer-sponsored rehabilitation program whenever required testing of an employee produces a positive drug test result places an unwarranted burden on the employer. HAI believes that an employer should have the right to dismiss an employee if any drug test conducted during employment produces a positive test result. HAI states that the employer should have the ability to decide which employees, based on the "value" of the employee to the organization, would be offered an opportunity for rehabilitation.

Small Part 135 certificate holders generally state that an employer should have the right to fire any employee who uses drugs and feel that an opportunity for rehabilitation should not be offered to any employee who uses drugs. These small employers base their position on the potential liability to the company of rehiring a known drug user, the expense to the company of holding the employee's job open, or replacing an employee on a temporary basis, during rehabilitation.

The AMA reaffirmed its long-standing support of employment-based treatment and assistance programs for employees with alcohol or drug problems. The AMA believes that the FAA should require an employer to provide one opportunity for rehabilitation to any employee who voluntarily enrolls in an EAP and to any employee who is identified as a drug user through testing.

NTSB generally concurred in the concept of requiring an employer to provide EAP services to employees. The

NTSB recommended that employers be required to offer one opportunity for rehabilitation to employees who volunteer for an EAP and for employees who are identified as drug users through any type of drug testing.

Most small business entities, TEMSCO Helicopters, Inc. and Overseas Air Transport Corporation for example, object to a regulatory provision that would require an employer to provide job security to an individual enrolled in rehabilitation. This objection is based on the financial burden of keeping a job open for an employee who is unable to perform his or her duties and the elimination of an employer's discretion to fire an employee who uses drugs. RAA believes that an employee who has successfully completed rehabilitation, as determined by the head of the rehabilitation program and airline management, should be offered an opportunity to return to duty. Executive Air Fleet (EAF), a Part 135 certificate holder with 200 employees subject to testing, would support job security for an employee who voluntarily sought rehabilitation and who had three to five years of service with the company. SSA also believes that an employee's length of employment may be a reasonable factor to consider when specifying an employer's obligation to retain or rehire an employee participating in rehabilitation. SSA also states that holding an employee's job open during inpatient rehabilitation will greatly complicate small business operations for an unknown time period. Henson Airlines states that, under its existing program, employees will be fired as a result of a positive alcohol or drug test. ERA Aviation, Inc. strongly objects to any Federally-mandated rehabilitation and rehire requirement. ERA Aviation objects to the cost of providing EAP services, but more important, objects to assuming the potential liability problems that could result from rehiring a known user of illegal substances even if that employee has successfully completed a rehabilitation program.

Several small operators, including TEMSCO Helicopters, Inc., object to the requirement to provide an opportunity for rehabilitation to employees identified as drug users. Henson Airlines provides an opportunity for rehabilitation only to employees who voluntarily enroll in rehabilitation. RAA supports these views. Organizations such as the American Association of Airport Executives (AAAE) and ATA believe that an opportunity should be offered only to employees who volunteer for rehabilitation. SSA states that there should be no requirement that a small business retain or rehire any

employee who tests positive for drugs as a result of any unplanned drug test, including postaccident or for-cause testing. ATA believes that limiting rehabilitation and reemployment to volunteers has the dual effect of making safety the industry's highest priority and containing the costs associated with rehabilitation. AAAE believes that any employee who tests positive for drugs should be dismissed immediately. AAAE comments that employers and employees should be free to negotiate broader rehabilitation and reemployment rights as part of a collective bargaining agreement.

Labor organizations are strong supporters of broad EAP opportunities and services. TWU and FEIA believe that all employees who test positive, regardless of the reason for testing, should be given at least one opportunity for rehabilitation. FEIA supports the requirement for at least one rehabilitation opportunity because a positive drug test is not proof of impairment on the job. The Teamsters Union believes that negotiated, client-specific rehabilitation programs should be available to employees who volunteer and for employees who test positive on one occasion. Labor organizations comment that all rehabilitation costs should be paid by the employer either directly or as part of an employee benefit or insurance package. TWU concurs with this position, insofar as it relates to the first positive test result, unless the employee has engaged in conduct that would otherwise justify suspension or discharge under an applicable collective bargaining agreement.

ALPA states that there is no valid reason to limit access to an EAP only to employees who volunteer for rehabilitation. Based on experience in the HIMS program, only 15 percent of the pilots treated for alcoholism were self-referred; 85 percent of the pilots were discovered by the union or management, or both. ALPA believes that rehabilitation should be made broadly available to any employee who could benefit from an EAP and that, in some cases, a second opportunity for rehabilitation may be appropriate. ALPA urges the FAA to revise the proposed regulation to require employers to pay the cost of rehabilitation programs that are mandated by the regulation.

ALPA believes that traditional EAP techniques that are tailored to a specific population, such as the HIMS program, will be more effective in deterring drug use than the anti-drug program proposed in the NPRM. During the 15-year period

that the HIMS program has been in effect, 800 pilots have participated in rehabilitation for alcoholism yielding a long-term success rate of 93 percent. ALPA states that the average "off line time" for pilots involved in the HIMS program is approximately 120 days: 30 days for treatment; 30 days for aftercare treatment, observation, and processing; and 45 to 60 days for processing of an FAA application. The recovery rate for pilots who participate in one rehabilitation opportunity is 85 percent. Of the 15 percent of the pilots who suffer a relapse after the first treatment, approximately 50 percent are successfully treated in their second rehabilitation opportunity.

**FAA Response.** Most comments regarding rehabilitation deal with the issue of whether, and under what circumstances, to offer rehabilitation and to provide job security to an employee and the length of any employee rehabilitation period. The FAA carefully considered the various arguments submitted by the commenters on the issue of EAP services and rehabilitation opportunities for employees. The FAA understands, and considered, the arguments raised in defense of broad rehabilitation opportunities and job security for aviation personnel who use drugs.

However, the FAA reviewed the two options that included provisions providing broad rehabilitation opportunities and job security to employees whose drug use was detected through testing under the final rule. Many of the commenters oppose rehabilitation opportunities and job security for employees who fail to discontinue drug use and wait to be detected by testing. The FAA agrees with these commenters and believes that a strong message must be conveyed to drug users that the use of drugs is unacceptable in the aviation industry. The FAA's primary duty, pursuant to statutory mandate, is to consider the adverse safety consequences surrounding the issue of drug use by sensitive safety- and security-related aviation personnel. On this basis, the FAA has determined that employers should not be obligated to offer an opportunity for rehabilitation or to provide job security to employees who fail a drug test or who use drugs on the job. The FAA understands that broad rehabilitation opportunities and job security for employees, without regard to the manner of detection of drug use, may help those employees who are unable to help themselves. But, the FAA believes that it is inconsistent with the agency's safety responsibilities to

promote the message that drug use in the aviation industry will be tolerated until an individual's drug use is detected through testing. The FAA believes that it is inappropriate to place the agency and an employer in the anomalous position of allowing any employee who uses illegal drugs to work in a sensitive safety- or security-related position and whose drug use may adversely affect aviation safety. Rather, the FAA believes that it is appropriate and consistent with its statutory safety mandate to prohibit an employee who fails a drug test, who refuses to submit to a drug test, or who uses drugs on the job from acting in a sensitive safety- or security-related position. The FAA is convinced that the comprehensive testing program of sensitive safety- and security-related employees, combined with an employee assistance program to educate and train all personnel, is consistent with the statutory duty to promote aviation safety and will reduce any drug use in the aviation community.

The FAA also carefully reviewed the third option presented in the NPRM that would provide an opportunity for rehabilitation and job security to an employee who admitted his or her drug use and who volunteered for rehabilitation before being detected through drug testing. However, in the FAA's opinion and as noted by the commenters, there are several issues related to employee rehabilitation and retention or reemployment benefits that must be considered in development of the final rule.

For example, the term "rehabilitation" generally means the period of time during which an employee is receiving treatment or counseling for a drug problem. The length of any rehabilitation period is dependent on several factors such as the availability and enrollment period of rehabilitation services, the length and extent of treatment for the level of use and the type of drug used, collection and analysis of tests given during rehabilitation, and the review process that may lead to a recommendation to return to duty in a sensitive safety- or security-related position. The term "rehabilitated" generally means that an employee is determined to be drug free and, based on the employee's progress and prognosis during rehabilitation, the employee may return to work. The fact that an employee has returned to work does not mean that the employee is exempt from follow-up or aftercare treatment and counseling.

The FAA is aware of the wide variety of rehabilitation programs that vary both in the length of treatment and type

of treatment depending on the substance used and the availability of rehabilitation and treatment services. One standard rehabilitation and treatment program, generally necessary for those individuals who require intensive inpatient care followed by outpatient care and counseling sessions, specifies 28 days of inpatient care. Other programs may involve shorter periods of time for inpatient care, may involve outpatient treatment only, or may involve a combination of inpatient and outpatient care of varied duration. For example, some treatment programs may require three to four sessions, given on two or three nights a week, over a six to eight week period and followed by less frequent meetings or counseling sessions. Other treatment programs might involve individual or group counseling sessions on a weekly basis, over a period of one year or more. An additional factor that affects the length of treatment or rehabilitation is the availability of private or community services in a particular area.

The FAA reviewed these variables to determine if a timeframe for voluntary rehabilitation and job security could be developed and included in the final rule. The FAA carefully considered the comments from many aviation businesses that oppose any regulatory requirement to offer rehabilitation and to retain or rehire any employee who admits to illegal drug use. The commenters base their objections on several factors including elimination of an employer's discretion to terminate an employee; undue complication of operations due to potential extended absences of employees enrolled in rehabilitation; and negation of an employer's ability to tailor rehabilitation opportunities and job security to a particular employee population. The most strenuous objections are based on the substantial and unwarranted burdens, both administrative and financial, associated with rehabilitation and job security for employees. Based on financial information submitted by the commenters, it appears that expenses of rehabilitation and job security opportunities as proposed would seriously affect large aviation entities and would probably overwhelm small companies.

After review of the considerable variables in treatment and the extensive arguments presented by the commenters, the FAA concluded that a reasonable accommodation of burdens on employers who may not be able to absorb employee absences and realistic opportunities for employee rehabilitation can not be imposed in the

abstract. Thus, the FAA does not agree with the commenters who state that the FAA should specify an opportunity for rehabilitation and the amount of time during which an employer is required to provide job security for an employee enrolled in rehabilitation.

Many employers in the aviation industry currently offer rehabilitation opportunities and job security benefits to employees. The FAA anticipates that those employers will continue to offer these opportunities and benefits to employees and that other employers may elect to include these components in any negotiated employee benefit package. Because many aviation entities have resolved the relative administrative, personnel, operational, and financial issues that surround employee rehabilitation and job security requirements, the FAA believes that the aviation industry is able to design appropriate programs and services for its employees. The FAA believes that, in light of the variables and burdens addressed above, issues regarding an adequate amount of time for rehabilitation, an appropriate amount of time to receive a recommendation to return to duty in a sensitive safety- or security-related position, and job security matters, are best addressed in the specific employment context.

Thus, an employer is not required to offer an opportunity for rehabilitation, to provide job security, or to provide the resources for rehabilitation to any employee. At the same time, employers may offer these opportunities and benefits to employees; the FAA urges employers to consider the experience of employers who have developed rehabilitation programs.

The final rule does not prohibit an employer from reassigning an employee to a position that does not involve the performance of sensitive safety- or security-related duties. The final rule also does not dictate whether an employee is required or permitted to use vacation time, sick leave, or leave without pay in order to accommodate the employee's time away from his or her sensitive safety- or security-related position. The FAA believes that issues such as termination, reassignment, hiring of temporary employees to fill a position, or policies regarding an employee's absence from a position, are issues that are appropriately the subject of employer and employee negotiation or collective bargaining.

The NPRM did not propose to require an employer to pay for an employee's rehabilitation and final rule also does not address this issue. Indeed, since an employer is permitted to terminate an employee who fails a drug test or who

refuses to submit to a drug test, and such employee does not have a right to return to duty for that employer, this issue is not relevant to the final rule. However, the employer may cover an employee's rehabilitation expenses through an employee benefit package, insurance coverage, or as a matter of collective bargaining negotiated between the employer and the employee. The FAA considers these areas to be a matter between employers and employees and, as such, are left to the discretion of the employer or to be negotiated during collective bargaining.

**EAP Education and Training Programs.** ATA states that the FAA should not specify the details and contents of an employer's EAP. The Teamsters Union believes EAP services should be negotiated between labor and management and that rehabilitation programs should be client-specific.

ALPA believes that EAP services should be tailored to be specific employee population as the HIMS program is tailored to pilots in commercial aviation.

Various labor organizations conclude that EAPs, instead of mandatory testing, are the preferable method to conduct an anti-drug program. AFA also urges the FAA to separate the administration of any drug testing programs, if mandated at all, from administration of an EAP.

The FAA received considerable data in response to the ANPRM and the NPRM regarding the availability of EAP services. Some of these commenters included specific, existing EAPs that are recommended by the industry. The Association of Labor-Management Administrators and Consultants on Alcoholism, Inc., (ALMACA) submitted an extensive, recommended industry EAP in response to the ANPRM.

Although most commenters think that EAPs are valuable, employer and employee organizations differ on the mechanics and content of an EAP education and training component. Labor unions generally favor broad EAP services. The majority of employer organizations favor EAPs that are designed to meet the specific needs of the company and oppose regulatory action by the FAA in this area.

**FAA Response.** The FAA believes that an employer should have the ability to design an EAP that would best serve its employees. The ability to tailor an EAP is particularly important for small aviation employers who may not have the financial and administrative resources to support a company-sponsored EAP. Therefore, the FAA has made no changes to the proposed minimal EAP education requirements. However, the FAA has revised the EAP

training requirements. The FAA deleted the minimum requirement of 60 minutes of annual training for all employees. The FAA retained the 60-minute training requirement for supervisors who will make determinations to test an employee based on reasonable cause. The FAA believes that it is appropriate to require a full 60 minutes of initial training for presently-employed and newly-hired supervisors making reasonable cause determinations because of the need for increased awareness and recognition of signs that may indicate drug use. The employer has the discretion to determine the reasonable recurrent training for supervisory personnel who have the authority to make reasonable cause determinations. The FAA believes that this flexibility will enable employers to address specific issues or needs that may arise as a result of the employer's anti-drug program.

The rule permits an employer to develop and provide these minimum services as part of an internal program or the employer may contract with community agencies or other aviation companies to provide these services to employees. The employer is permitted to provide additional education and training, beyond the minimum requirements of the rule, to its employees. The FAA believes that employers will not have substantial difficulty developing education and training programs for employees because of the significant number of model EAPs submitted to the FAA in response to the ANPRM.

**Small Aviation Entities and Businesses.** The National Air Transport Association (NATA) represents numerous Part 135 certificate holders in the aviation industry. NATA states that the anti-drug program would have significant cost impact on Part 135 certificate holders and, particularly, small aviation operators. NATA recommends that Part 135 certificate holders, with 100 or fewer covered employees should be excluded from the requirement to submit and implement an anti-drug program. A number of other small Part 135 certificate holders responding to the NPRM also argue for exclusion from the anti-drug program.

AOPA urges the FAA to exempt from the rule operators and their employees who currently are exempt from the requirements of Part 135. AOPA contends that these operators are invariably small businesses who would be unable to withstand the financial and administrative burdens of the proposed regulations. Several commenters involved in single pilot—single aircraft

operations noted the difficulty of complying with most of the provisions of the proposed rules.

Atlantic Aero, Inc., a fixed based operation employing more than 100 people, and Sunwest Aviation support efforts to address the drug problem but state that modifications to the proposal are necessary to avoid an unjustified administrative and financial burden on small operators.

SSA feels that the proposed anti-drug program is inappropriate for small businesses that rely on student instruction as the economic base of activities or for certified flight instructors acting as independent contractors. SSA believes that the FAA has failed to account for the practical differences between large corporate entities and small businesses. SSA suggests that the FAA develop four separate anti-drug programs that would address the particular needs and concerns of Part 121 certificate holders, Part 135 certificate holders, flight schools, and small businesses or independent contractors.

A commenter speaking as national litigation counsel for AOPA and on behalf of the California Aviation Council and the Orange County Aviation Association, conveys the concerns of flight instructors, small fixed base operators, banner towers, crop dusters, and other small aviation entities that do not provide scheduled air carrier service who are affected by the proposal. This commenter notes that the NPRM is an unwarranted, overreaching invasion of the domestic aviation community's right to be free from governmental intrusion because of the lack of evidence of any drug problem among commercial aviation professionals. The commenter states that this lack of evidence supports the history or responsible self-regulation by the commercial aviation community.

The National Association of Flight Instructors (NAFI) states that the anti-drug program proposed in the NPRM is tailored for a large aviation organization and, therefore, is not appropriate for a small organization or a freelance flight instructor that is not employed by any company. NAFI believes that testing of a flight instructor each time that instructor performs flight instruction duties will be impossible. In addition, NAFI is concerned about the quality and reliability of laboratory analysis; the constitutionality of drug testing; and the administrative and economic burden on small entities related to EAP services, MRO requirements, and job security for employees enrolled in rehabilitation. Two individual commenters believe that sole-proprietorships and businesses that

employ 10 or fewer employees should be excluded from any requirement to implement an anti-drug program.

**FAA Response.** The FAA understands the economic and practical concerns expressed by Part 135 certificate holders as well as those entities or individuals, listed in § 135.1(b), who are otherwise exempt from the requirements of Part 135 but are affected by the regulation because they are engaged in operations for compensation or hire. For the purposes of the requirements of the anti-drug program, the FAA has tailored the final rule in an attempt to accommodate small aviation entities, particularly those Part 135 certificate holders who employ 50 or fewer employees who are covered by this final rule and those entities or individuals, listed by this final rule and those entities or individuals, listed in § 135.1(b), who are otherwise exempt from the requirements of Part 135 but are included in the comprehensive anti-drug program because they conduct operations for compensation or hire.

The FAA believes that it would be counterproductive to the goals of the anti-drug program to impose requirements on small aviation entities who would be unable to comply with them because of substantial financial, administrative, and logistical difficulties. The vast majority of the difficulties are associated with the requirements of implementing a random testing program and providing rehabilitation programs and services to employees. Therefore, the FAA has revised the proposed rule to provide a tiered implementation plan that would allow small aviation entities to develop and implement a comprehensive anti-drug program, over specific time periods, in accordance with a schedule determined by the FAA. The language of the rule does not prohibit an employer from implementing its anti-drug program sooner than required by the FAA's schedule if the employer is able to comply with the rule requirements and the provisions of its anti-drug program at an earlier date.

Part 121 certificate holders and Part 135 certificate holders that have more than 50 covered employees, and contractors to these certificate holders, will be required to follow the schedule that was proposed in the NPRM with one exception. As proposed, these employers must submit an anti-drug plan to the FAA not later than 120 days after the effective date of the rule and must implement the anti-drug program not later than 180 days after approval of the anti-drug program by the FAA. However, these employers are required to implement preemployment testing of

applicants for sensitive safety- or security-related positions not later than 10 days after approval of the employer's anti-drug plan by the FAA. The FAA believes that it is appropriate to require accelerated implementation of preemployment testing for these employers because many of these employers have existing preemployment testing programs and, generally, these employers have the available financial and administrative resources that enable them to begin testing.

Part 135 certificate holders that have 11 to 50 covered employees, and contractors to those certificate holders, will be required to submit an interim anti-drug program, that sets forth all required drug testing except mandatory random drug testing, not later than 180 days after the effective date of the final rule. The employer must implement preemployment testing, periodic testing, postaccident testing, testing based on reasonable cause, and testing after an employee's return to duty not later than 180 days after approval of the anti-drug program by the FAA. These employers must submit an amendment of their interim anti-drug program to the FAA, that contains the procedures for implementing an unannounced testing program of employees who are randomly selected at the applicable annualized testing rate, not later than 120 days after approval of the interim anti-drug program by the FAA. The employer must continue implementation of the remainder of the program and must implement the random testing provision not later than 180 days after approval of the amended anti-drug program by the FAA.

Part 135 certificate holders with 10 or fewer covered employees and those entities or individuals, listed in § 135.1(b), who are otherwise exempt from the requirements of Part 135 but are included in the comprehensive anti-drug program because they conduct operations for compensation or hire, and any contractors to these employers, must submit an anti-drug plan to the FAA for approval, that includes procedures for all types of testing mandated by the rule, not later than 360 days after the effective date of the final rule. These employers must implement the approved anti-drug program not later than 180 days after approval of the plan by the FAA. The FAA believes that this extension of time will enable small aviation entities to evaluate random drug testing programs of other companies, to develop an appropriate method by which to comply with the drug testing provisions of the rule, and to participate in any association or

consortium that may be available to provide specimen collection, testing assistance, and EAP services. Also, the FAA believes that it is appropriate to require these employers to submit a plan that includes random testing, as opposed to implementation of random testing after other testing is implemented, because these employers will have a significant amount of time to develop and implement a comprehensive anti-drug program for their employees.

New aviation businesses that come into existence after the effective date of the rule, and that are subject to the requirements of the final rule, will be required to comply with the schedule that is appropriate for the size of the company and their particular operations. The FAA believes that it is appropriate to adhere to the same time schedules that are set forth for existing aviation entities in order to treat similarly-situated entities in a similar manner. However, it is possible that the timeframes may be accelerated for new businesses in the future as existing employer programs and consortia develop and continue to provide services to the aviation community.

The FAA has identified an issue that could unduly burden small commercial operators who do not hold a Part 121 certificate or a Part 135 certificate, who conduct operations listed in § 135.1(b), and who are included in this final rule because they conduct operations for compensation or hire. Under the terms of the proposed rule, these commercial operators would have been unable to contract for aircraft maintenance or preventive maintenance services. The proposed rule would have prohibited commercial operators from using the services of employees who work for fixed base operators and repair stations that service only general aviation aircraft if the employees of these entities were not subject to an FAA-approved comprehensive anti-drug program. In an effort to relieve this unintended burden, the FAA has included a new provision in the final rule directed solely at those individuals or entities. This provision states, in essence, that an individual who is otherwise authorized may perform maintenance and repair work on a commercial operator's aircraft, even if that individual is not covered by a comprehensive anti-drug program, in two specific instances. First, an individual who is not covered by the final rule can perform emergency repairs on an aircraft if the aircraft could not be operated safely to a location where a covered employee could perform the repairs. Second, an individual who is

not covered by the final rule can perform aircraft maintenance and preventive maintenance repairs on an aircraft if the operator would be required to transport the aircraft more than 50 nautical miles further than the closest available repair point from the operator's principal base of operations in order to have the work performed by a covered employee. The FAA believes that this narrow exemption from the requirements of the final rule will benefit the small commercial operators subject to the final rule but will not adversely affect the enhanced aviation safety intended by the final rule.

**Medical Review Officer (MRO).** Several small entities, including EAF, believe that an MRO should have the responsibility to determine if an employee has been successfully rehabilitated and to determine when an employee may return to duty. ATA also recommends that an MRO be involved in the determination of an employee's successful rehabilitation. However, ATA notes that it would not always be feasible for an MRO to personally interview each employee who has a positive test result and recommends that the final rule accommodate that situation. RAA and Federal Express oppose any regulatory provision that would require an airline to appoint or to designate an MRO as part of an anti-drug program.

APFA believes that an MRO should be an independent physician who could assist labor and management EAP officials during analysis of drug test results and determination of the validity of test results in each employee's case. AFA believes that it is imperative that an MRO have specific training in toxicology and addictive diseases. Even with this training, AFA believes an MRO should be responsible for monitoring any testing program and interpreting test results to determine if referral to an EAP is warranted for a particular employee. AFA states that evaluation and referral for treatment and determinations regarding an employee's readiness to return to work should be made only by an EAP treatment professional. IUFA states that only the health care professional with whom an employee has been working is qualified to make a determination of when an employee is fit to return to duty. If an MRO and the responsible health care official disagree, a neutral third party should evaluate an employee and determine if an employee is fit to return to work. ALPA states that the determination of whether an individual has been rehabilitated, at least in the case of pilots, must be made by the

Federal Air Surgeon under the medical certification procedures contained in Part 67 of the Federal Aviation Regulations.

**FAA Response.** In response to commenters who oppose the requirement to designate or appoint an MRO, the FAA notes that the rule does not require that each employer have its own individual MRO. The FAA anticipates that small companies will become part of, or will associate with, large companies or may participate in a consortium of small companies or associations, in order to comply with the MRO requirement of the final rule that will result in reasonable costs to small employers.

After consideration of the comments on the issue of MROs, the FAA has determined that the requirements proposed in the NPRM are appropriate. The FAA believes that the review and evaluation functions of an MRO provide critical and necessary safeguards for an employee who is subject to drug testing under the comprehensive anti-drug program. The FAA believes that the MRO will prove to be a beneficial asset to both employees and employers who are subject to the provisions of the final rule.

However, the FAA has expanded the role of the MRO after review of the comments and the proposed rule, although many of these responsibilities are contingent on an employer's decision to be involved in rehabilitation. For example, if an employer chooses to use an individual to perform a sensitive safety- or security-related function who has failed a drug test under this program and who has successfully completed rehabilitation, the MRO will develop an unannounced testing schedule for that individual. The MRO is the final arbiter in cases where an individual disputes a testing schedule after return to duty. Except in cases where the Federal Air Surgeon is involved, as discussed below, the MRO also is the final arbiter regarding return-to-duty recommendations. The MRO also shall review any rehabilitation program in which an employee or an applicant participated, after failing a drug test conducted in accordance with Appendix I to Part 121, to determine if an employee can return to duty or an applicant may be hired to perform a sensitive safety- or security-related function for an employer.

The FAA also has defined the factors that an MRO shall consider when making a return-to-duty determination. The MRO is required by the final rule to ensure that an individual is drug free as evidenced by a drug test; that an

individual has been evaluated by a rehabilitation counselor for drug use or abuse; and that an individual has complied with testing and counseling requirements of a rehabilitation program. Thus, the MRO will have significant and sufficient information to recommend, based on the MRO's professional opinion, that an individual or a current employee could perform a sensitive safety- or security-related function for an employer.

The FAA clarified the proposed requirement that the MRO "conduct a medical interview" with an employee as part of the review of a positive test result. The FAA did not intend that the proposal require a face-to-face interview with each employee. The final rule requires that the MRO provide an employee with an opportunity to discuss a positive test result with the MRO. Thus, for example, the MRO is permitted to discuss the positive test result with the employee by phone. The FAA believes that the clarification will relieve some administrative burdens on the MRO and employees in scheduling discussions of a positive test result. The FAA also added several requirements to the MRO's list of duties. First, the MRO is required to notify an employee of a confirmed positive test result within a reasonable time after verification of the result. Second, the MRO must process an employee's request to retest a specimen. The final rule provides that the employee's request to retest must be made in writing to the MRO within 60 days of notification of the confirmed positive test result.

In the NPRM, the FAA requested comment on who should make the decision that an employee had been successfully rehabilitated and could return to duty if the employee was drug free. ALPA specifically comments that return-to-duty determinations of pilots should be made by the Federal Air Surgeon consistent with the medical certification procedures contained in Part 67 of the Federal Aviation Regulations. Part 67 of the Federal Aviation Regulations define "drug dependence" as a "condition in which a person is addicted to or dependent on drugs other than alcohol, tobacco, or ordinary caffeine-containing beverages, as evidenced by habitual use or a clear sense of need for the drug." After review of the comments and consideration of the medical standards contained in Part 67, the FAA has determined that the Federal Air Surgeon must be involved in the decision to return an individual who holds a Part 67 medical certificate to a sensitive safety-related position. The FAA believes that

it would be contrary to the statutory mandate to determine the physical ability of an individual to perform duties pertaining to his or her airman certificate if the FAA failed to participate in a return-to-duty decision for an individual who holds a medical certificate.

Thus, the FAA has clarified the responsibilities of the MRO for situations where an employer voluntarily becomes involved in rehabilitation of employees or persons hired to perform sensitive safety- or security-related functions that require an individual to hold a medical certificate issued by the FAA. Under the rule, the MRO will perform all the duties and make all the determinations required in Appendix I for those individuals who do not hold a medical certificate issued pursuant to Part 67 of the Federal Aviation Regulations. For those individuals whose position with the employer requires them to hold a Part 67 medical certificate, the MRO is required to make a preliminary determination, consistent with the standard contained in Part 67, of probable drug dependence or a determination of nondependence. If the MRO makes a determination of nondependence based on his professional opinion, the MRO may recommend that an employee return to duty in a sensitive safety- or security-related position. The MRO is required to forward the finding of nondependence, the decision to return the employee to duty, and any supporting documentation, to the Federal Air Surgeon for review.

The FAA is aware that allowing an MRO to determine that an individual is not drug dependent and, therefore, may return to work in a sensitive safety- or security-related position without prior clearance by the Federal Air Surgeon may be controversial and may be viewed as inconsistent with aviation safety. However, in the FAA's opinion, it is consistent with aviation safety to provide subsequent FAA review of the treatment and any medical determination of nondependence that has been made by a competent licensed physician with knowledge of substance abuse disorders. The FAA also believes it is beneficial to provide subsequent review of an MRO's return-to-duty determinations, rather than initial review by the Federal Air Surgeon, so that an individual who is not dependent on drugs can return to work as soon as possible. Moreover, any individual who returns to work after rehabilitation is subject to unannounced testing as determined by the MRO and may be

subject to ongoing counseling. Therefore, the FAA believes that initial determinations by an MRO and subsequent review by the Federal Air Surgeon will result in effective and fair treatment of individuals who are required to hold a medical certificate.

At any point that an MRO, in this professional opinion, makes a determination of probable drug dependence of an individual required to hold a medical certificate for a position, the MRO is required to report the name and other identifying information, and to forward all documentation that supports the determination, to the Federal Air Surgeon. If the MRO has made a probable drug dependence determination of an individual required to hold a medical certificate, the MRO may not make a recommendation to return that individual to duty. From that point forward, the Federal Air Surgeon is responsible for determining whether the individual may keep a medical certificate or may be issued a medical certificate consistent with the medical standards contained in Part 67 of the Federal Aviation Regulations. Since drug dependency is a disqualifying medical condition under Part 67 of the Federal Aviation Regulations, it is critical that the Federal Air Surgeon be aware of any determination of probable drug dependence. An individual subject to the medical requirements of Part 67 who has a history of drug dependency must receive a "special issuance" medical certificate, issued at the discretion of the Federal Air Surgeon pursuant to § 67.19, before returning to work in a sensitive safety-related position. The Federal Air Surgeon is required to determine if that individual is qualified to hold a medical certificate and is physically able to exercise the privileges of an airman certificate. This determination, and the discretion to grant a special issuance of a medical certificate, clearly are within the exclusive expertise of the Federal Air Surgeon.

The FAA has added a provision to the final rule that requires the MRO to report the name of any current employee required to hold a medical certificate to perform a sensitive safety-related function who fails a drug test. The MRO also is required to report the name of any individual who holds a medical certificate and applies for a position with the employer in which a medical certificate is required and who fails a preemployment drug test. The MRO is required to report the names of these individuals to the Federal Air Surgeon because a positive drug test result clearly is probative evidence of possible

drug dependence which is a disqualifying condition under the medical standards of Part 67 of the Federal Aviation Regulations. Therefore, the FAA added this requirement to ensure that the FAA is aware of conditions that may affect an individual's ability to physically perform the duties of an airman.

*Administrative Matters and Reporting and Recordkeeping Requirements of Appendix I to Part 121.* The FAA received very few comments regarding the reporting requirements of the proposed rules. ATA found the requirements of Appendix I to be acceptable. ATA recommended that the FAA establish a date to analyze the data collected regarding drug testing and rehabilitation and to review the regulations. Suburban Airlines, as part of its analysis of the costs of the proposals, estimates that the administrative costs and record retention costs of testing its 211 employees would be \$8,500 per year. Federal Express supports auditing of annual, summary data by the FAA that is supplied by an employer regarding the employer's anti-drug program. Federal Express does not object to submitting an anti-drug program for the FAA's approval but believes that the 180-day implementation period will be insufficient if the final rule contains all of the requirements proposed in the NPRM.

*FAA Response.* The regulatory provision that require an employer to submit a comprehensive anti-drug program and summary reports of the employer's program are critical measures to provide oversight of the industry's implementation of the comprehensive anti-drug program. The FAA believes that these minimal requirements are necessary to properly monitor the industry and to ensure compliance with the final rule. In addition, evaluation of the industry's implementation of the anti-drug program and the results of testing and rehabilitation programs will enable the FAA to review any demonstrated trends of drug use in the aviation industry and to modify the rules if warranted by the data. These reporting requirements are consistent with the FAA's existing industry recordkeeping and reporting requirements.

The FAA has modified the proposed recordkeeping and reporting provisions in the final rule. First, the FAA has clarified the requirements and organization of material that must be submitted in the employer's semi-annual report and annual report. In order that the FAA may accurately assess

information submitted by an employer, the revised final rule provides that the employer must submit the total number of tests performed; the total number of tests performed for each category of test; and the total number of positive test results for each category of test given by an employer. These requirements are in addition to the proposed requirement to provide information on the number of positive test results according to the function performed by an employee for each type of test and according to the type of drug indicated by a positive drug test result. The FAA anticipates that requiring an employer to report the additional information will not overburden an employer because drug testing laboratories commonly report the bulk of this information when reporting drug test results. For example, as part of the DOT procedures (49 CFR Part 40), a DHHS-certified laboratory is required to provide a monthly statistical summary of initial and confirmation urinalysis testing data of employees tested during the month to the person responsible for coordination of the drug program. The summary contains information on the number of specimens received for initial and confirmation testing; the number of specimens reported for initial testing; and the number of specimens reported positive for each of the five drugs or drug metabolites tested during initial and confirmation testing [DOT "Procedures for Transportation Workplace Drug Testing Programs;" 49 CFR Part 40].

The FAA had proposed that an employer only keep records relating to the specimen collection process in the NPRM. However, in light of other revisions to the proposed rule made in response to the comments, the employer also must retain records of test results and records relating to any employee rehabilitation. For example, the MRO is required to report the names of individuals holding a Part 67 medical certificate who fail a drug test and to forward test result and rehabilitation information regarding all individuals holding a medical certificate to the Federal Air Surgeon. Thus, the FAA has revised the recordkeeping provision of the proposed rule to require that an employer keep adequate information with which an employer and the FAA can evaluate the anti-drug program and determine any trends that may develop in the commercial aviation industry. Pursuant to the final rule, an employer is required to retain all confirmed positive test results and any rehabilitation records for five years. The employer may retain these records longer than

five years although extended record retention is not required by the final rule. The FAA also added a provision to the final rule that requires an employer to keep any negative test results for a period of 12 months. However, all records retained by the employer are subject to limited release, as discussed below, for any period of time that the employer keeps these records.

*Confidentiality of Test Results.* Most small businesses, individuals, and labor unions support restrictions on the release of drug testing information. These commenters believe that the FAA should include a regulatory provision prohibiting the release of any drug testing information about an employee.

RAA believes that only the employer and the employee should have access to the results of the anti-drug program. Conversely, ERA Aviation suggests that employers should be required to report the name, social security numbers, and certificate numbers of employees testing positive to the FAA. TWU states that test results should be confidential as to all persons, except an applicant or employee, absent written consent or valid compulsory process. The laboratory may release confirmed positive test results or negative test results only to the employer's medical officer. TWU suggests that the medical officer may notify managerial or supervisory personnel who have a compelling need for the information to implement employer's policies or may notify the medical personnel responsible for an employee's rehabilitation.

RAA and Federal Express believe that job applicants should be required to disclose prior test results to subsequent employers as a condition of employment. ATA believes that records of applicants for employment who have tested positive in a preemployment drug test should be disclosed to third persons in limited situations, including authorization from the applicant, litigation by the applicant, pursuant to a valid subpoena, and by order of a court or administrative agency. However, ATA believes that test results, related personnel records, and rehabilitation data of incumbent employees should not be released to any person absent express consent of the employee. The Director of the Santa Maria Public Airport District believes that positive test results of all employees and applicants should be retained in a central database and should be available to potential aviation employers. Federal Express also believes that carriers should be free to exchange an employer's drug testing

results and that the FAA should insulate carriers from liability for this disclosure.

ALPA states that information regarding an employee's drug testing history should be treated as confidential information, and clearly stated in any final rule, since it is "extracted" from the employee by requiring the employee to submit to drug testing. A rule of confidentiality should apply to all information obtained pursuant to the regulation whether obtained as a result of testing, interview, or examination, or treatment of an employee. ALPA believes that the only effective and appropriate rule is a complete ban on disclosure of confidential drug testing information without the employee's written consent. ALPA believes that a complete ban on disclosure is required for ethical reasons and to encourage candor by employees when dealing with medical professionals.

As a general matter, EEAC advocates protecting the privacy of individuals who undergo drug tests. EEAC believes that sharing of drug testing information among employers in a safety-sensitive industry has superficial appeal. However, EEAC advocates caution in allowing a subsequent employer to rely solely on information obtained as a result of a different company's drug testing procedures.

**FAA Response.** The FAA has included a provision in the final rule that will govern release of records of an employee's drug testing results and any rehabilitation information. The FAA has decided that the legitimate individual privacy rights of an employee warrant strict limitations on the availability of an employee's drug testing results and rehabilitation information. The final rule provides that the release of an individual's drug test results and any information about an employee's rehabilitation program is permitted only with the specific, written consent of the individual. Due to the specific provisions discussed previously, this restriction does not override the requirement to report test results and any rehabilitation information to the Federal Air Surgeon of an applicant or an employee who holds a medical certificate who fails a drug test. The final rule also provides that the FAA is entitled to examine these records and that this information must be released to the NTSB as part of an accident investigation or to the FAA upon request.

**Temporary Employees.** The FAA solicited comments in the NPRM on the proposed definition of temporary employees and their eligibility for rehabilitation. RAA agrees with the FAA's proposed definition that temporary employees are those

individuals who are hired for a period of less than 90 days. ATA and Federal Express propose a period of 120 days and TEMSCO Helicopters proposes a period of 150 days or less to determine an employee's eligibility for rehabilitation opportunities.

RAA and ATA agree with the FAA's proposal to exclude temporary employees from rehabilitation opportunities. RAA and ATA oppose the FAA's proposal to consider employees, who are eligible for reemployment by the same employer within 90 days following the original employment, as regular employees of the industry and, therefore, eligible for rehabilitation opportunities if they are rehired by the airline.

Several organizations, including TEMSCO Helicopters and ATA, comment that the time period of 90-day employment would adversely affect businesses who employ individuals on a seasonal or contract basis for longer periods of time. SSA states that small businesses should not be required to retain or to rehire a part-time or temporary employee who volunteers for, or otherwise participates in, rehabilitation.

**FAA Response.** In the NPRM, the FAA requested comment on the definition of a temporary employee and whether employers should be required to offer rehabilitation opportunities and job security to temporary employees. After consideration of the comments and due to deletion of the requirement to offer rehabilitation and job security to employees, a definition of temporary employees in the final rule is unnecessary. Therefore, an employer is not required by the rule to offer an opportunity for rehabilitation or to hold a position open for any temporary employee.

However, the final rule makes no distinction regarding testing of temporary employees. Thus, an employer is required by the final rule to include temporary employees in its drug testing program. The burden of testing temporary employees is slight when compared to the significant risk that a temporary employee who uses drugs poses to aviation safety. Thus, the FAA believes that it is important to test temporary employees for the presence of drugs or drug metabolites that may adversely affect performance of a sensitive safety- or security-related function. Many "temporary" employees, who actually are recurring seasonal employees or are regularly and continually rehired at the end of specified term, are "permanent" members of the aviation industry. The FAA firmly believes that these

individuals clearly should be included in an employer's drug testing program in the interest of aviation safety. In addition, these employees, although they may consistently perform sensitive safety- or security-related functions pursuant to short-term contracts for different employers, should be included in EAP education programs because of their continuous involvement in commercial aviation activities.

**Uniformity versus Flexibility.** ATA, American Airlines, Delta Airlines, IUFA, and IFFA believe that all employers and employees should be subject to uniform minimum rules and requirements in the area of drug testing. These entities strongly believe that company-specific plans may dilute the effectiveness of the anti-drug program or lead to harassment of employees.

EEAC supports the concept of employer flexibility to design specific anti-drug programs. EEAC believes that each employer should determine the circumstances of employee drug testing and the content of employee assistance programs. EEAC supports preemployment testing, postaccident testing, periodic testing incident to scheduled physical examinations, and testing based on reasonable cause. EEAC believes employers should have the option of requiring random testing of employees.

EEAC readily endorses EAP services and rehabilitation of employees but believes that these benefits should not be mandated by the government. Decisions whether an employee has been rehabilitated and whether an employee should be permitted to return to work should be determined by the individual employer acting with the guidance of professionals involved in an employee's rehabilitation.

Federal Express believes that use of controlled substances at any time, whether on or off the job, should be prohibited due to the critical safety concerns in the aviation industry. Federal Express states that such a prohibition " \* \* \* helps ensure safe operation of aircraft and protects employees and the general public from unnecessary safety hazards." However, Federal Express believes that the FAA should impose only minimum regulatory requirements of a drug testing and rehabilitation program and allow carriers to structure individual programs for their particular employees.

**FAA Response.** The FAA agrees with the Commenters who conclude that mandating minimum, uniform requirements for comprehensive anti-drug programs in the commercial aviation industry is necessary in order

to maximize the effectiveness of the program and to achieve a safe and drug-free commercial aviation workforce. The FAA believes that the comprehensive anti-drug program promulgated in this final rule meets the agency's statutory mandate to promote the safety of civil aircraft operating in air commerce and that it responds to the public's need for a safe aviation environment.

In response to the comments, particularly in the area of anti-drug programs implemented by small aviation entities, the FAA has addressed the need for employer flexibility by revising the program requirements or the implementation dates. The FAA has not included specific, detailed provisions regarding the content and requirements of an individual's treatment due to the significant variables that affect these components based on each individual, the type of drug used, and the level of any drug use, drug dependence, or drug addiction. Thus, in the area of an employee's rehabilitation treatment plan, the FAA agrees that this decision is best left to the discretion of those individuals who are significantly and directly involved in the employee's rehabilitation.

The FAA has imposed uniform, minimum requirements on employers and employees in other areas of the comprehensive program. Although employers are required to comply with the minimum requirements, employers may expand the minimum testing requirements to include other employees or may offer EAP services and rehabilitation opportunities to employees. If the employer expands its anti-drug program, any additional components of the employer's anti-drug program may not contradict or dilute the effectiveness of the FAA's final rule. As stated in the NPRM, while the FAA would not prohibit employers from taking independent actions beyond those required by the rule, such actions may not adversely affect the final rule and would not be authorized by the FAA. Therefore, additional benefits or more stringent procedures would not be considered part of the employer's approved program.

The FAA received many comments for revision of the final rule to include testing for additional drugs and permission for an employer to use analytical procedures that are not addressed in the DHHS guidelines. The Department of Transportation will address the issue of testing for additional drugs in the DOT "Procedures for Transportation Workplace Drug Testing Programs" (49 CFR Part 40). DOT intends to follow the proposed

DHHS guidelines which allow testing for other drugs, in addition to the five drugs specified in the appendix, only in the context of testing based on reasonable cause. Neither this final rule nor the DOT procedures address the issue of an employer's ability to test for drugs, other than the drugs specified by the FAA, to the extent that an employer has independent legal authority to test for other drugs.

**Regulatory Consent.** AOPA believes that the FAA should eliminate the regulatory section that would require a pilot to submit to a drug test requested by an employer, a local law enforcement officer, or an FAA inspector. AOPA asserts that the FAA does not have the authority or the expertise to administer a drug test and that refusal to submit to a test is best left to local law.

ATA agrees with the sanctions proposed for an employee's refusal to submit to a required test. Henson Airlines has an existing policy that an employee's refusal to submit to a drug or alcohol test will result in disciplinary action that could include dismissal from the company.

**FAA Response.** The FAA has not revised the provisions proposed in the NPRM that would provide sanctions for an employee's refusal to submit to a drug test required as part of the comprehensive anti-drug program. The FAA believes that the sanctions proposed in the NPRM are appropriate and are necessary to ensure compliance with the requirements of the anti-drug program. In response to AOPA's comment, the FAA would not "administer" a drug test under this provision. The FAA would simply request that the employee submit to a drug test, collected and analyzed consistent with the DOT procedures of 49 CFR Part 40, where testing would be otherwise authorized under an anti-drug program. This provision is necessary primarily in the area of postaccident drug testing where the FAA may be the only official at the scene of an accident with the authority to request that an individual submit to a postaccident drug test.

The FAA also believes that compliance with the testing requirements of the final rule is not an issue that is best left to local law. As a preliminary matter, the FAA has clear statutory authority to promote and maintain aviation safety. Second, the FAA is the entity that issues airman certificates and that is charged with ensuring that an airman is qualified to exercise the privileges of that Federal certificate. Finally, sanctions imposed pursuant to State or local law may vary

widely among each jurisdiction and would subject similarly-situated employees to dissimilar treatment according to the content of the local law. Therefore, the FAA believes that it is appropriate to provide that an individual is disabled from performing a sensitive safety- or security-related function and to include sanctions for a failure to submit to a drug test to promote aviation safety and to ensure consistent treatment of individuals engaged in commercial aviation.

**Existing Regulations.** AOPA, several small aviation entities, and many individual commenters believe that the FAA's existing regulations, and increased FAA enforcement of these regulations, are sufficient to deal with any drug problem in the aviation industry.

A commenter speaking as national litigation counsel for AOPA and on behalf of the California Aviation Council and the Orange County Aviation Association believes that the types of testing proposed by the FAA are duplicative of the existing opportunities for testing in the periodic medical examination of commercial and air transport pilots. In addition, this commenter states that the FAA has the authority, pursuant to § 609 of the Federal Aviation Act, to reexamine or reinspect any airman at any time. Therefore, the commenter believes that the FAA could implement a lawful drug testing program within the existing infrastructure of the FAA's certification procedures. The commenter also states that the regulations proposed in the NPRM create an irreconcilable conflict with the FAA's safety-enhancement enforcement system. The commenter believes that the proposed anti-drug program will prove detrimental to aviation safety because the number of enforcement cases brought by the FAA for violations of the proposed regulations will overburden the FAA and the administrative law judges assigned to hear enforcement cases.

**FAA Response.** The FAA disagrees with the commenters who state that the comprehensive anti-drug program requirements are redundant and that increased enforcement of the existing regulations or reexamination of individual airmen will result in a drug-free commercial aviation environment. The existing regulations do not address the issue of drug testing of aviation personnel performing sensitive safety- or security-related functions in commercial aviation. Thus, in the FAA's opinion, enforcement of existing regulations or individual reexamination will not sufficiently deter any drug use

in commercial aviation. In addition, the existing regulations do not address the critical issues of procedural safeguards in collection and testing of samples for the presence of drugs or drug metabolites that are provided in the DOT procedures of 49 CFR Part 40.

Establishing a drug testing program within the existing "infrastructure" of the existing certification procedures is equivalent to implementing only a periodic testing requirement. Because of an individual's ability to circumvent periodic testing, based on a relatively short abstinence from drug use, periodic testing alone is not a sufficient deterrent to drug use in commercial aviation. The FAA believes that it is appropriate and necessary to provide minimum requirements, applicable to employers and employees, that will achieve a drug-free commercial aviation environment.

**Preemption of State and Local Laws.** ATA, Federal Express, and RAA recommend that the FAA insert a regulatory provision that explicitly proscribes State or local legislation that would interfere with the consistent and uniform testing and rehabilitation opportunities for aviation employees mandated by this final rule.

**FAA Response.** The FAA agrees with the commenters who are critically concerned about conflicting State and local laws that would interfere with an effective comprehensive anti-drug program. The FAA believes that inconsistent laws or regulations applicable to the subject matter of this final rule will frustrate the intent of the rule and severely hamper implementation and administration of an anti-drug program. Therefore, the FAA has included a preemption provision in the final rule that is intended to enhance the efficiency and effectiveness of the requirements of the final rule.

The FAA's issuance of the final rule preempts any State or local law, rule, regulation, order, or standard that covers testing of commercial aviation employees for the presence of drugs or drug metabolites. The new rule does not preempt any State law that imposes sanctions for the violation of a provision of a State criminal code related to reckless conduct leading to actual loss of life, injury or damage to property, whether such provisions apply specifically to aviation employees or generally to the public. The scope of the authority preempted by this final rule and the authority reserved to the States is essentially identical to the provision in the regulations issued by the Federal Railroad Administration of the Department of Transportation (49 CFR 219.13).

**Waivers or Exemptions.** ATA believes that waivers and modifications of an employer's drug testing program should be granted if exceptional circumstances warrant the waiver or modification and if an equivalent level of safety can be maintained under the terms of the waiver. American Airlines advocates that all carriers should be subject to identical requirements and waivers should not be granted.

**FAA Response.** The final rule sets forth minimum requirements that must be included in an employer's anti-drug program. However, the rule generally does not set forth detailed program administration requirements in most areas of the program. Also, an employer is not prohibited from establishing an anti-drug program that goes beyond the minimum requirements promulgated by this rule. As a result of the FAA approval process of an employer's anti-drug program, a certain amount of discretion and flexibility is retained for an employer's administration of its anti-drug program.

On this basis, the FAA has determined that any requests for exemption from a requirement of this rule should be handled in the same manner as requests for exemptions of other FAA regulations under Part 11 of the Federal Aviation Regulations. The FAA believes that a case-by-case determination will be necessary to ensure that any exemptions from the requirements of this final rule are in the public interest.

#### Contractors

The FAA has revised the proposed rule as it applies to contractors whose employees perform sensitive safety- or security-related service for aviation entities subject to the rule. Under the proposed rule, contractors whose employees perform covered service to aviation entities were authorized to submit their own plans to the FAA to implement directly an anti-drug program. These contractor employees also could have been included in the anti-drug program of the aviation entity for whom they were providing services. However, for the final rule, the FAA concluded that all persons performing sensitive safety- or security-related functions should be under the plan of the aviation entity for whom they provide the services.

The FAA believes that administration of the anti-drug program would be vastly more efficient—for aviation entities directly subject to the rule, contractors, and the FAA—by reducing the proliferation of different plans submitted by a significant number of contractors who provide covered service

to the same aviation entity. In addition, the FAA believes that limiting the submission of plans to those aviation entities directly subject to the rule will provide a more consistent approach to administration of industry anti-drug programs and will minimize the difficulties of ensuring compliance with the final rule. As noted earlier in this preamble, the final rule provides that an employee who is subject to the requirements of any employer's FAA-approved anti-drug program may provide sensitive safety- or security-related services to any other employer. Therefore, so long as a contractor employee is covered by one aviation entity's anti-drug program, the employee would be able to provide services for any employer subject to the rule. Thus, a contractor whose employees provide services to multiple aviation entities would not be subject to any greater burden than those entities directly subject to the rule.

#### Additional Issues

**Alcohol.** The NTSB, AMA, Henson Airlines, and other individual commenters suggest that the FAA include alcohol as a tested substance in any required testing program.

The FAA expressly excluded the issue of alcohol testing from this rulemaking for a variety of reasons stated in the NPRM; therefore, these comments are beyond the scope of this rulemaking. Excluding alcohol testing from this rulemaking should not be construed to mean that the FAA is ignoring the fact that alcohol may be a substance of widespread abuse in the aviation industry. As stated in the NPRM, the FAA will continue to review the effectiveness of regulations dealing with the issue of alcohol use and abuse in aviation and may consider additional rulemaking action in the future. In addition, employers are not prohibited from initiating alcohol testing programs for their employees if not otherwise prohibited from testing for alcohol.

The Department of Transportation will include a provision in the DOT procedures (49 CFR Part 40) that will enable an employer to test for the presence of alcohol in an employee's system. Pursuant to those procedures, the employer could include testing for alcohol in testing protocols only pursuant to FAA approval if the testing is authorized under the FAA regulations.

**Testing for additional drugs.** The NTSB recommends that the FAA expand the list of prohibited drugs to include those substances listed in Schedule III and Schedule IV of the Controlled Substances Act. The NTSB also

recommends that the FAA develop a medical exemption process to provide for a pilot's legitimate medical use of these substances. ATA recommends that mind-altering prescription drugs, such as barbiturates, benzodiazepines, methadone, and methaqualone, also be listed as prohibited drugs in any drug testing program. ERA Aviation supports this recommendation and suggests that propoxyphene, quaaludes, and codeine be added to the list of drugs that would be screened.

The five drugs specifically listed in Appendix I to Part 121 are the five drugs for which DHHS has set cutoff levels and testing protocols in its mandatory guidelines (53 FR 11970, 11973-11974; April 11, 1988). The Department of Transportation intends to adopt these cutoff levels and testing protocols verbatim in its procedures applicable to the aviation industry (49 CFR Part 40). An employer is required to test for marijuana, cocaine, opiates, phencyclidine (PCP), amphetamines, and metabolites of those drugs because of the incidence and prevalence of use of these drugs in the general population and based on the experience of the Department of Defense and the Department of Transportation in their drug testing programs. Because analysis of additional, less-frequently used drugs could result in substantial additional expense, the FAA believes that requiring an employer to test for these five drugs is appropriate at this time. Any testing for other drugs, beyond the specified drugs listed in the appendix, is authorized only in the context of testing based on reasonable cause. Only if, in that context, the FAA authorizes testing for additional Drug X under 49 CFR Part 40 (an approval which would be granted only after consultation with the Department of Health and Human Services, and only on the basis of an HHS-established testing protocol and positive threshold) may the employer also test the sample for that drug.

Absent such an approval, if the employer wants to test, in addition, for Drug Y, the employer must obtain a second sample from the employee. The obtaining of this second sample is not under the authority of the DOT regulation. The employer must base its request for the second sample on whatever other legal authority is available, since the employer cannot rely on the DOT regulation as the basis for the request.

The FAA is aware that listing the drugs that will be analyzed as part of a drug testing program may result in individuals using alternative drugs that are not analyzed pursuant to the final

rule. As part of the agency's review and analysis of the industry's anti-drug programs, the FAA encourages the aviation industry to notify the FAA if different drugs are being used in the aviation community. As part of the FAA's oversight of the comprehensive anti-drug program, the FAA will seek statistical information, to the extent any information is available, from the National Institute on Drug Abuse (NIDA), other Federal agencies, and any other source to determine if additional, different drugs should be included in the comprehensive anti-drug program to ensure aviation safety.

*Testing of other individuals.* Several commenters, including the AMA, NTSB, ATA, and ALPA, suggest that the FAA expand the list of individuals to be tested, or defined as sensitive safety- and security-related employees, under the regulations. Several entities recommended that the FAA require testing of all individuals certificated by the FAA, including general aviation pilots. ALPA, ATA, and Martin Aviation recommend that any employee who performs a function in or around an aircraft (deicing, weight and balance computation, fueling, taxiing or towing aircraft, weather forecasting, baggage handlers, and cargo personnel) and supervisors of covered employees be subject to testing because these individuals affect aviation safety. Federal Express states that it would include ramp agents responsible for weight and balance of an aircraft, deicers, and fuelers in a drug testing program. Federal Express supports inclusion of aviation security screeners in a drug testing program although it does not employ these individuals. ALPA and American Airlines also urge the FAA to include corporate officers in any testing program. The Director of the Santa Maria Public Airport District suggests that the FAA amend Part 107, Part 108, and Part 139 to ensure that employees of certificated airport operators are included in the anti-drug program. Tramco, Inc. suggests that Part 145 be amended so that repair station employers are required to comply with the anti-drug requirements in the same manner as Part 121 certificate holders. Tramco also suggests that aircraft manufacturers be required to implement an anti-drug program.

After review of these various comments, the FAA has retained the basic regulatory list of functions proposed in the NPRM. However, the FAA has eliminated parachute rigging duties from the list of functions contained in Appendix I to Part 121. The activities performed by parachute

riggers do not have a direct and significant impact on the safe operation of civil aircraft as do the other sensitive safety- and security-related functions listed in the appendix.

The FAA has not revised the rule to require drug testing of supervisory or managerial employees. However, the FAA notes that under the proposed rule and the final rule, supervisory or managerial employees who perform sensitive safety- or security-related functions for an employer are not permitted to perform these functions, either on a permanent or temporary basis, unless those employees are subject to the requirements of the employer's anti-drug program. Also, repair station employers and employees are subject to the requirements of an anti-drug program if these individuals provide contract service to an employer who is subject to the requirements of this final rule. Under the terms of the rule, a Part 121 certificate holder, a Part 135 certificate holder, or an entity or individual covered by the rule because they operate for compensation or hire may only use the services of persons who are subject to the requirements of an FAA-approved program. Therefore, although Part 145 was not amended, repair station employers and employees are included to the extent that they provide contract service or repair aircraft operated by an employer subject to the final rule.

The comprehensive anti-drug programs, proposed by the operating administrations within the Department of Transportation, focus on drug testing for various commercial transportation activities. The scope and direction of the FAA's comprehensive anti-drug program is consistent with the present Department-wide policy.

The FAA encourages the public and members of the aviation industry to submit information to the FAA (directed to the person listed in the heading "FOR FURTHER INFORMATION CONTACT") that may warrant inclusion of different drugs in a drug testing program or additional categories of employees to be tested. If it is necessary to preserve confidentiality of any information submitted to the FAA, the FAA encourages aviation industry representatives or trade associations to transmit the information to the FAA. The FAA will monitor the data gathered pursuant to this program, and will continue to review other information regarding drug use in private and commercial aviation, to determine if further rulemaking action in this area is required or necessary. The FAA may revise other sections of the Federal

Aviation Regulations, to broaden the applicability and scope of the comprehensive anti-drug program, if further study warrants this action. The final rule does not prohibit an employer from testing any other employee or group of employees, if the employer is not otherwise prohibited, that the employer determines should be tested for drugs to provide safety or efficiency in the workplace.

*Conflict with foreign laws or policies.* We have determined not to make the rule applicable in any situation where compliance would violate the domestic laws or policies of another country. In addition, because of the potential confusion that may exist involving application of this rule in situations where compliance could violate foreign laws or policies, we have determined not to make the rule applicable, until January 1, 1990, in any situation where a foreign government contends that compliance with our rule raises questions of compatibility with its domestic laws or policies. During the next year, the Department of Transportation and other U.S. government officials will be working closely with representatives of foreign governments with the goal of reaching a permanent resolution to any conflict between our rule and foreign laws and policies. The U.S. and Canadian Governments have already established a bilateral working group in an attempt to achieve this objective. We believe that considerable progress has already been made, and further meetings will be held in the near future. While we believe that this can be a model for addressing the concerns of other countries, it is not intended to be the exclusive means. The Administrator may delay the effective date further under this section, if such delay is necessary to permit consultation with any foreign governments to be successfully completed.

It is the agency's intention to issue a notice no later than December 1, 1989, that would make any necessary amendments to the rule as a result of discussions with foreign governments. Shortly after their issuance, any such notices will be published in the *Federal Register*. While we recognize that any decision not to apply our rule to foreign citizens has the potential to create some anomalous conditions in competitive situations, it is the intention of the U.S. Government to make every effort to resolve potential conflicts with foreign governments in a manner that accommodates their concerns while ensuring the necessary level of safety by those we regulate.

*Statutory authority.* One commenter questions the authority of the FAA to promulgate regulations that proscribe recreational drug use by any airman during his or her free time that does not impair the airman's performance on the job. As stated by the commenter, the FAA's mandate is to ensure the safety of civil aviation and not to enforce criminal drug enforcement laws.

The FAA clearly has the statutory authority to mandate continuing eligibility requirements and minimum physical and medical standards to promote and develop safety in air commerce and civil aeronautics. For example, the FAA has clear authority to prohibit off-duty consumption of alcohol prior to aircraft operation to ensure that a crewmember is not impaired by alcohol while acting or attempting to act as a crewmember of a civil aircraft. Similarly, in the FAA's opinion, this broad authority includes the authority and ability to prohibit the presence of any drug or drug metabolite in an individual's system that may adversely affect aviation safety.

As noted in the NPRM, it often is difficult to detect the subtle and varying degrees of drug impairment to motor skills and judgment that are critical to aircraft operation or performance of sensitive safety- and security-related duties. Certain drugs or drug metabolites remain in an individual's system long after use and may impair an individual's subsequent performance. Indeed, the Vice President of a national firm providing consultation services on drug abuse prevention to American Airlines, with significant experience in identification and treatment of drug users, states that marijuana use disrupts recall and short-term memory and that there is serious impairment of skills appropriate to industrial operations for 10 to 12 hours after smoking a single marijuana cigarette. The FAA believes that it is clearly in the public interest and within the FAA's statutory authority to ensure that any "hangover effect" associated with recreational use of illegal drugs does not interfere with an individual's performance and, thus, jeopardize air safety.

#### *Summary of Significant Changes From the Proposed Rule*

The FAA amended several sections of the proposed rule in response to comments received from the public on the issues and in response to questions raised in the NPRM. Any changes that significantly altered the requirements of the anti-drug program are discussed previously and are summarized in this section.

The definition of an "employee" in Appendix I to Part 121 was amended to make it clear that employees of an entity that holds both a Part 121 certificate and a Part 135 certificate are to be considered employees of the Part 121 certificate holder. This will ensure that all employees of a single entity, regardless of the type of operating certificate held by the employer, are subject to the same requirements and time schedules for the purposes of an anti-drug program.

The definition of "employer" also was amended. This section was amended to make it clear that an employee of one company that has implemented an anti-drug program may perform sensitive safety- or security-related functions for another employer. For example, a mechanic employed by American Airlines, who is covered by American's anti-drug program, is permitted to perform maintenance duties or repair work on an aircraft owned by United Airlines.

The Department of Transportation has determined that certain modifications of the DHHS guidelines, proposed in the NPRM, are appropriate for this rulemaking. The FAA has referenced a DOT interim final rule (49 CFR Part 40), entitled "Procedures for Transportation Workplace Drug Testing Programs," in this final rule.

The FAA did not revise significantly the section of the appendix regarding the substances for which testing must be conducted. However, the appendix provides that testing for drugs listed in Schedule I and Schedule II of the Controlled Substances Act is permitted only during testing based on reasonable cause. In addition, the testing must be conducted in accordance with the DOT "Procedures for Transportation Workplace Drug Testing Programs" and pursuant to the employer's approved anti-drug program.

The FAA clarified the preemployment testing provision to make it clear that an employer may use a person to perform a sensitive safety- or security-related function who passed a previous preemployment drug test for an employer and has continuously been subject to testing under an approved anti-drug program even if the individual is not currently employed by that employer. The rule prohibits an employer from "hiring" any person after failing a preemployment drug test. The rule does not require an employer to test every applicant but only to test an applicant before he or she is actually hired by the employer.

The periodic testing provision was revised to make it clear that an

employee is only required to provide one specimen for testing during the employee's first periodic medical examination in the first calendar year of implementation of the final rule. Also, this section was revised to enable an employer to discontinue periodic drug testing of employees as part of a medical examination after the first full calendar year of implementation of the employer's anti-drug program. After the first year of implementation, the employer's random testing program should be fully implemented and periodic testing as part of a medical examination may be eliminated.

The FAA revised the random testing provision of the final rule in response to the comments and with reference to the plans of the random testing program started by the Department of Transportation. The final rule provides for phased implementation of unannounced testing based on random selection beginning with an annualized rate equal to 25 percent of covered employees during the first 12 months of program implementation. Thereafter, the employer must achieve and maintain an annualized testing rate equal to 50 percent of the covered employees. The FAA also added a provision that would enable an employer to randomly select employees for unannounced testing based on a method, other than the methods originally proposed in the NPRM, that has been approved by the FAA.

The FAA has amended the postaccident testing provision. The revised section requires an employer to ensure that postaccident testing is conducted as soon as possible but not later than 32 hours after an accident.

As discussed previously, the FAA has expanded the bases upon which an employer may substantiate the determination to test an employee based on reasonable cause. In order to address concerns expressed in the comments, the FAA has included a provision in this section that allows a small aviation employer to test an employee based on a determination of reasonable cause made by only one supervisor trained in detection of drug use symptoms. As proposed in the NPRM, an employer may test an employee performing a sensitive safety- or security-related function for any Schedule I or Schedule II drug, if the employer conducts the testing based on reasonable cause in a manner consistent with the employer's approved anti-drug program and the DOT procedures (49 CFR Part 40).

In response to comments specifically solicited in the NPRM, the FAA has included a provision for unannounced testing after an employee's return to

duty. Employees who failed a drug test or who refused to submit to a drug test and who have not received a recommendation to return to duty from an MRO must be tested in accordance with the return-to-duty provision of the final rule. This section requires an employer to implement a reasonable program of unannounced testing, for not longer than 60 months, after an individual has been hired or an employee has returned to duty to perform a sensitive safety- or security-related function.

The FAA has expanded the role of the medical review officer (MRO). For example, the MRO will review rehabilitation programs to determine if an employee may return to duty or an individual may be hired to perform a sensitive safety- or security-related function for an employer. The MRO also is the final arbiter in the case of disputes regarding a schedule for unannounced testing after an employee's return to duty. The FAA has added several provisions to this section to describe the duties of an MRO and the involvement of the Federal Air Surgeon where an individual who holds a medical certificate tests positive for the presence of a drug or drug metabolite.

The FAA has added a provision that protects the confidentiality of employee drug testing results and any rehabilitation information. This information may be released by an employer only with the written consent of the employee. However, the FAA may examine test result and rehabilitation records and the information may be released to the NTSB as part of an accident investigation or to the FAA upon request.

For various reasons discussed previously and in response to many comments, the FAA determined that opportunities for rehabilitation and job security for employees will not be mandated by this final rule. Rehabilitation opportunities and job security issues may be considered by an employer and should be determined by employers and employees in the specific employment context.

The FAA has tailored the schedule proposed in the NPRM for submitting an anti-drug program to the FAA and implementation of an anti-drug program in response to comments received in response to the NPRM. These changes have been fully discussed previously. In essence, the large aviation companies are required to comply with the schedules proposed in the NPRM. Smaller aviation companies have additional time to develop and implement an interim anti-drug program and slightly broader timeframes to

develop and submit a random testing program. The smallest aviation entities covered by the rule initially have additional time to develop and implement testing programs for their employees.

The FAA also has included a section in Appendix I to Part 121 to provide for the preemptive effect of these regulations regarding any State or local law covering the subject matter of drug testing of commercial aviation employees. However, issuance of the final rule does not preempt State criminal laws that impose sanctions for reckless conduct leading to death, injury, or property damage.

#### *Comments on the Cost of the Anti-Drug Program*

Most small entities object to the anti-drug program based on the financial and administrative burden that these entities believe would result from implementation of the rule as proposed. Executive Air Fleet (EAF) is a Part 135 certificate holder with 200 employees who would be covered by the proposed rules. Because drug testing is widespread in other industries, EAF states that the aviation industry should "move ahead" with the proposed rules. However, EAF states that the potential costs of an anti-drug program could be burdensome even to an operation the size of EAF. EAF estimates that drug testing as proposed in the NPRM would cost \$25,000 annually to test its 200 covered employees. EAF services would cost up to \$26 per employee. EAF believes that EAP services would have to be available to the total employee population, not only sensitive safety- or security-related employees, because it is a benefit offered to employees. Thus, EAF estimates that EAP services for a business employing 400 individuals would cost \$10,400 annually.

Metro Air is a Part 135 certificate holder using two single-engine aircraft, two light twin-engine aircraft, and three helicopters. Metro Air also is a flight school operator using 15 aircraft. Metro Air employs six full-time pilots and four to five part-time pilots. Metro Air states that the proposed rule is not financially feasible for small commercial operators because the company is not in a position to retain or offer rehabilitation to an employee who tests positive for drugs and the cost of hiring an MRO to interpret test results would be prohibitive. Metro Air believes that the FAA should conduct all drug testing of employees and administer any rehabilitation offered to an employee.

Ryder Systems, Inc. employs over 40,000 individuals who perform a variety

of jobs in the transportation industry. Ryder Systems implemented an EAP in 1984. Ryder Systems estimates that 40 percent of the employees enrolled in the EAP due to controlled substance abuse problems require 28- to 30-day inpatient treatment that costs between \$10,000 to \$20,000. The average cost for controlled substance rehabilitation per employee is \$3,000. On this basis, Ryder Systems believes that the FAA should only require that an employer establish an EAP and offer EAP services to an employee but should not specify the details of an EAP or rehabilitation program. However, Ryder Systems believes that the FAA should preserve the employer's discretion to determine EAP eligibility standards for employees, treatment of repeat offenders, and the conditions for allowing an employee to return to work.

American Airlines estimates that rehabilitation and treatment of an employee costs \$8,000. For this reason and to ensure that the quality of treatment will lead to a reasonable prognosis for recovery, American Airlines believes that employers and contractors should be financially responsible for rehabilitation. Conversely, RAA and several small aviation entities, including Martin Aviation, Inc., believe that the FAA should not force airlines to incur the cost of employee rehabilitation due to the economic impact of the requirement on the regional airline industry.

RAA states that the average cost of a single random test would be \$55 and that retesting for verification of positive results could cost up to \$80 per test. On this basis, RAA estimates that the cost of random testing at a rate of 125 percent annually for regional airline pilots only will approach \$500,000 annually. Due to the high cost of testing at a rate of 125 percent and the fact that the proposed rules would require testing of other aviation safety-related personnel in addition to pilots, RAA suggests that a random sampling rate of 50 percent would be appropriate.

Suburban Airlines employs 211 employees who would be covered by the proposed program. Suburban estimates that the FAA's program would cost over \$28,000 annually at present employment levels. Based on Suburban's experience, 5 percent of initial tests indicate positive results for the presence of drugs and must be confirmed to verify the initial test results. Tramco, Inc., a certificated repair station, estimates that compliance with the anti-drug program will cost \$24,000 annually plus counseling and lost time costs.

ALPA believes that the FAA incorrectly estimated the cost of the

proposed anti-drug program and, therefore, the drug testing program is not justified by any reasonable cost-benefit analysis. ALPA states that the laboratory cost per test, assuming a random testing rate of 125 percent and a negotiated cost similar to the cost contained in the economic analysis, is merely a fraction of the total costs associated with a drug testing program. ALPA maintains that a drug testing program could cost at least \$280 million per year. ALPA's estimate of cost is based on substantial administrative and personnel expenses, transportation of employees to a collection site, employee compensation during collection of a specimen, and compensation of employees who replace employees being tested during revenue flights.

A commenter speaking as national litigation counsel for AOPA and on behalf of the California Aviation Council and the Orange County Aviation Association believes that the FAA understated the costs and overgeneralized the benefits of the proposed rule contained in the economic summary of the NPRM. This commenter also believes that the FAA failed to consider more effective, practical, and less intrusive programs to deal with any drug problem that might exist in the aviation industry. The commenter states that the economic analysis fails to consider the potentially destructive economic effect of the proposed rules on small, commercial operators. Therefore, the commenter states that the FAA may not issue a final rule because the FAA has failed to meet the criteria of Executive Order 12291.

California Aeromedical Rescue and Evacuation, Inc. (CARE) does not believe that the proposed rules are reasonable due to the lack of evidence of a drug problem in aviation. CARE comments that the cost of maintaining a drug testing program, whether or not that program includes random testing, is significant. CARE employs 10 pilots, 4 mechanics, and approximately 45 flight nurses and flight medics. CARE estimates that the cost per test is \$45 and, therefore, the fiscal impact on its operations will be between \$8,000 to \$12,000 per year. CARE believes that its scarce financial resources should be used for training, equipment, and maintenance. CARE states that preemployment and probable cause testing are wise and prudent measures. CARE predicts that including other types of testing will cause some of its employees to leave the company due to issues related to the constitutionality of unannounced testing without particularized suspicion of drug use. CARE states that the costs of litigation

and training for new employees should be directed to other more useful avenues.

The commenters stress that while the costs developed by the FAA may be appropriate for larger companies, who are able to take advantage of "economies of scale," small aviation companies would incur significantly higher costs.

Two commenters who submitted a joint comment on the economic analysis contained in the NPRM dispute the benefits of the proposals in the NPRM, particularly with the FAA's estimate of the possible detection rate. These commenters present statistical analyses, using the data in the NPRM on general aviation pilots, to demonstrate, in their opinion, a considerably reduced detection rate and, therefore, considerably reduced benefits.

**FAA Response.** The FAA agrees that costs of screening and confirmation tests may reflect the bulk purchasing power of laboratory service for a large number of specimens and, therefore, may be applicable only to large aviation companies. However, the FAA lacks clear and definitive data regarding the extent to which "economies of scale" will affect or reduce costs. Although some commenters believe that the FAA failed to consider costs associated with administration of the anti-drug program, the initial Regulatory Evaluation and the FAA's total costs stated in the NPRM included these administrative costs.

The figures in the NPRM were based on average industry costs available to the FAA at the time of the NPRM. The FAA believes that the costs contained in the NPRM may closely equate to actual costs because the vast majority of personnel subject to the testing requirements of the proposed rule, by a ratio of 10 employees of large companies to one employee of small companies, are employees of large companies. Moreover, the FAA notes that small Part 135 certificate holders and other small aviation companies often are associated with larger companies. The FAA believes that small aviation operators could participate with large companies, much as these small companies contract for maintenance, reservations services, gate agents of larger companies, to conduct the required tests pursuant to the rules and, thus, take advantage of the economies of scale.

Nevertheless, the FAA increased the estimate of drug testing costs in an effort to respond to the concerns expressed by the commenters and to reflect the potential testing costs incurred by small aviation operators. For the purposes of the Regulatory Impact Analysis of the

final rule, the cost estimate of screening tests was increased to \$25.00 per test; the cost estimate of confirmation tests was increased to \$35.00 per test; and the administrative costs were increased to \$35.00 per test.

The FAA recognizes that broad rehabilitation programs would be very costly and could be cost-prohibitive for small aviation companies. For a variety of reasons discussed previously, the final rule does not require an employer to offer an opportunity for rehabilitation to employees and the FAA has not mandated a minimum amount of time that an employer must hold a position open while an employee is prohibited from performing sensitive safety- or security-related functions.

In estimating the benefits that are expected to accrue as a result of a comprehensive anti-drug program, the FAA noted its lack of specific, available data in the NPRM. The FAA disagrees with the commenters who dispute the analysis of benefits provided by the FAA in the NPRM and notes that a comparison of the benefits determined by these commenters with the estimated costs of the rule would still result in a cost beneficial rule. No evidence is available to demonstrate that sole reliance on the data regarding deceased general aviation pilots is representative of the population of employees who are subject to testing under the provisions of the final rule.

Infrequent and sporadic data is available in the commercial aviation sector. The FAA can not rely solely on information deduced from the two commercial aviation accidents discussed previously. The information does not reveal any significant patterns that would assist the FAA's estimates of costs and benefits of the proposals and, in any event, this information is not generally representative of personnel who are not pilots but who are subject to the requirements of the rule. For these reasons, the FAA believes that it is appropriate to use the national NIDA study information to estimate the potential costs of the rule because it more accurately reflects the broad population of employees who would be tested pursuant to a comprehensive drug testing program.

#### Economic Summary

In accordance with the requirements of Executive Order 12291, the FAA reviewed the cost impact and benefits of this final rule. Cost factors were obtained from information in the public docket including comments received during the FAA's public hearings. Additional data were furnished by air carrier trade associations, public

institutions, and major chemical and drug testing laboratories. This rulemaking does not meet the criteria of a "major" rule under Executive Order 12291 because it is not likely to have an annual effect on the economy of \$100 million or more. A summary of the FAA's estimates of the costs and benefits is provided below. However, because the rulemaking is a costly undertaking, the FAA considers the final rule to be a "major" rule under Executive Order 12291. For this reason, the FAA prepared, and placed in the docket, a Regulatory Impact Analysis of the final rule. In addition, because the rule involves issues of substantial interest to the public, the FAA determined that the rulemaking is significant under the Regulatory Policies and Procedures of the Department of Transportation (44 FR 11034; February 2, 1979).

**Costs.** The FAA estimated that the requirements of the final rule, over the 10-year period from 1990 to 1999, will cost approximately \$240.3 million in 1987 dollars (an average of \$24.0 million per year) or approximately \$135.2 million discounted over that 10-year period. The discounted cost includes (rounded to the nearest million) \$97.1 million for random testing; \$6.2 million for periodic testing, postaccident testing, testing based on reasonable cause, and return-to-duty testing; \$8.6 million for preemployment testing; \$10.6 million for blind samples submitted to laboratories; \$10.3 million for EAP education and training cost; and \$2.4 million for costs associated with preparation and submission of an employer's anti-drug program.

Costs of postaccident testing, testing based on reasonable cause, and return-to-duty testing are included as part of periodic testing costs. The FAA used one-half of one percent of the estimated population tested annually as the number that will be tested under one of these three circumstances. The analysis of these costs is set forth in the full Regulatory Impact Analysis (Exhibit A) included in the public docket.

The final rule will affect 149 entities that hold Part 121 certificates, 3,614 entities that hold Part 135 certificates providing scheduled and on-demand service, and contractors who provide services to those certificate holders. The rule also will affect an undetermined number of entities engaged in operations listed in § 135.1(b) for compensation or hire. The FAA has been unable to determine the exact number of these organizations due to the highly diversified and multipurpose nature of their operations. For purposes of analyzing the cost impact of the final

rule on these entities, the FAA estimated that approximately 1,500 entities, the same number as repair stations, are engaged in operations listed in § 135.1(b) for compensation or hire. Based on these estimates, the FAA estimated that 538,000 persons will be subject to drug testing in 1991 pursuant to the requirements of the final rule.

The FAA estimated that the cost of an initial screening test for the presence of drugs or drug metabolites will be \$25 per test. The FAA expects that 12.5 percent of initial screening tests will require confirmation testing in accordance with the guidelines and standards contained in Appendix I to Part 121. Of the total initial screening tests, 7.5 percent are expected to be confirmed as true positives; 5.0 percent are expected to result in false positive test results after confirmation. The remainder are not expected to be confirmed as positive either because the specimen failed to meet the minimum threshold to be scientifically considered as positive, or because the specimen did not show the presence of drugs or drug metabolites. Confirmation tests are estimated to cost \$35 per test. The FAA notes that an employer can realize substantial savings by contracting with a drug testing laboratory for a fixed price that includes the cost of initial screening tests and confirmation tests rather than paying for these tests separately. For example, the Coast Guard currently pays a single, fixed price of \$21 for screening tests and any resulting confirmation tests under a single contract with a drug testing laboratory.

The FAA estimated that a screening test will require 15 minutes of a person's time to provide information for chain-of-custody forms and to provide a urine sample for drug testing. Thus, the FAA included a factor equal to 25 percent of an average, fully allocated, hourly wage for each occupational group covered by the final rule. The FAA also assumed that affected persons will provide urine samples for testing while on duty. The FAA included \$35 per test as an administrative cost to cover, among other things, collection of specimens, reporting and recordkeeping, and chain-of-custody procedure costs. The FAA recognizes that these costs can vary significantly depending on a number of variables. For example, specimens may be collected in a medical setting (i.e., in a hospital or a clinic, in the presence of medical doctors, nurses, medical technicians). Collection of specimens in a medical setting is not required by this rule. Less expensive settings and nonmedical personnel trained for specimen collection may be used by the

aviation industry. Collection sites may be either centrally located or dispersed throughout remote geographical locations. DOT's drug testing program and the FAA's periodic drug testing program illustrate the cost variations associated with specimen collection. DOT uses a contractor to collect specimens at various, dispersed locations throughout the country. DOT pays an average of \$123 for each specimen collected. Specimens collected as part of the FAA periodic testing program are collected by aviation medical examiners. Collection costs for periodic tests range from \$10 to \$45 per specimen. The FAA considered these costs when estimating the administrative costs of the final rule. After consideration of the cost variations, the estimated administrative costs are representative of the costs expected in the aviation industry. The FAA increased the administrative costs contained in the NPRM on the basis of information submitted by commenters. The FAA believes that the aviation industry will find the most economical method of sample collection and will do so at costs that most closely mirror the costs charged to the FAA by aviation medical examiners for collection of specimens for periodic testing.

In the case of most postaccident testing, testing based on reasonable cause, and testing after return to duty triggered by refusal to submit to a test or failure of a previous drug test, the FAA assumed that collection costs for these tests are the same as the collection costs for random tests. However, the FAA assumed that the cost associated with collection of a small percentage of postaccident specimens would be \$100 per test. The FAA used this higher figure to address the probability that postaccident specimens may be collected at a remote accident site or a location other than a site that the employer routinely collects specimens. Conversely, specimens collected for testing based on reasonable cause or testing after return to duty could be collected in a central location or at the same location where other specimens are collected pursuant to the requirements of the final rule.

**Benefits.** The FAA believes that three major benefits will result from the promulgation of the final rule. First, benefits will accrue from the prevention of potential injuries or fatalities and property losses due to accidents attributed to neglect or error on the part of employees performing sensitive safety- or security-related functions whose motor skills or judgment may be impaired by drugs. Second, benefits will

accrue based on the potential reduction in employee absences from work, lost productivity, reduced medical and insurance costs due to on-the-job accidents, and improved general safety in the workplace. Third, broad benefits in the development of air commerce will accrue from projected diminished drug use by commercial aviation employees, thereby increasing public confidence in the commercial aviation transportation industry.

A review of the commercial aviation safety record shows that drug use may have been a cause or factor in only two recent aviation accidents. One accident was in 1983 and involved an all-cargo operation. The second accident was in 1988 and involved a passenger operation. Both accidents have been described previously in this rulemaking document. Drug use has not been established as a definitive causal factor of either accident. In the absence of readily-available statistical data depicting the extent of drug use by employees in commercial aviation and in light of the pernicious effects of drug use, the FAA does not consider the existing safety record to be an exclusive and valid indicator of the threat to aviation safety posed by aviation employee drug use. However, allegations of drug use by the pilot and copilot of Continental Air Express Flight 2286 that crashed on January 19, 1988, killing 9 people, reveal the significant and real potential for fatal aircraft accidents that may be related to the use of drugs in commercial aviation. In light of data regarding drug use by mechanics and repairmen submitted in response to the ANPRM, the FAA also is concerned about the potential for aviation accidents attributable to drug use by commercial aviation maintenance personnel.

The FAA estimates that \$84.3 million in discounted benefits would result from promulgation of the final rule if one accident attributed to drug-impaired performance by an individual who performs a sensitive safety- or security-related function in commercial aviation, involving a narrow-body, three-engine, commercial aircraft carrying 133 passengers and 5 crewmembers, is prevented during the 10-year period from 1990 to 1999 (Exhibit E). Although not claimed as a benefit in this Regulatory Impact Analysis, the benefits associated with the prevention of a single accident, during the 10-year period from 1990 to 1999, would be considerably more if the accident involved a 4-engine, wide-body aircraft carrying 289 passengers and 19

crewmembers. In this event, discounted benefits would total \$219.9 million.

The FAA also attempted to estimate benefits of the final rule, other than those benefits that may result from the prevention of aircraft accidents, associated with diminished drug use by commercial aviation personnel or any drug-deterrent effect that would result from promulgation of the final rule.

These estimated benefits consist of improved employee productivity as a result of drug use deterrence. A report released in 1987 by the National Institute on Drug Abuse (NIDA), entitled "Strategic Planning for Workplace Drug Abuse Programs," reveals that drug and alcohol abusers are involved in an additional 3.6 more accidents than nonabusers; file 1.5 additional workers' compensation claims than nonabusers; file 2.5 times more often for sick leave of 8 or more consecutive days than nonabusers; and incur 3 times the amount of normal medical costs than nonabusers.

In the absence of pertinent data, the FAA assumed that the rate of drug use by the 538,000 covered aviation personnel is approximately the same as the rate of drug use in the general population (e.g., 10 percent). The FAA also assumed that the productivity of employees who use drugs is 95 percent of the productivity of employees who do not use drugs.

In order to be conservative in estimating the costs of the final rule, the FAA assumed that 7.5 percent of the covered aviation personnel would produce test results that are confirmed positive for prohibited drug use. However, this estimate is premised on testing that produces optimum detection rates and the fact that drug users may continue to use drugs despite implementation of a comprehensive drug testing program that includes unannounced testing based on random selection. Realistically, the FAA expects that testing pursuant to the final rule will not achieve optimum detection rates and that some drug users will cease to use drugs rather than face the consequences of being detected by testing under the final rule.

The FAA hypothesized that 1.0 percent of the affected aviation population will stop using drugs voluntarily in the face of a comprehensive drug testing program. These individuals are expected to continue to perform sensitive safety- or security-related functions without the presence of drugs or drug metabolites in their systems. As noted above, the FAA assumed that drug users are 95 percent effective at their jobs compared to

employees who do not use drugs. Thus, the aviation industry would realize a 5 percent on-the-job productivity increase for each individual who ceases to use drugs. Therefore, the FAA estimated that employee productivity gains of \$97.3 million, or \$54.3 million discounted over the 10-year period from 1990 to 1999, will accrue to the aviation industry based on the reduction of illegal drug use and increased employee productivity (see Exhibit G).

**Benefit/Cost Comparison.** The total cost of compliance with the requirements of the final rule is estimated to be \$240.3 million in 1987 dollars and \$135.2 million, at a present worth discount rate of 10 percent, over the projected 10-year period from 1990 to 1999. The FAA has been unable to quantitatively estimate the accident prevention effectiveness of the final rule. Nevertheless, the FAA believes that drug use, unless stemmed, will continue to pose a threat to aviation safety. The FAA estimates that preventing one accident involving an average size, commercial, passenger aircraft during the 10-year period from 1990 to 1999 would result in discounted benefits of \$84.3 million. Likewise, discounted benefits ensuing from increased employee productivity are estimated to be \$54.3 million. Thus, total discounted benefits expected to result from promulgation of the final rule amount to \$138.6 million. The benefit to cost ratio of the final rule is 1.03.

#### Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 requires a Federal agency to review any final rule to assess its impact on small businesses. In consideration of the cost information discussed previously and included in the full Regulatory Impact Analysis, the FAA certifies that the final rule may have a significant negative economic impact on a substantial number of small entities. In an effort to relieve the burden on small entities, the FAA modified the requirements of the final rule and provided alternative schedules and implementation periods directed solely at small aviation entities to provide some measure of relief from the costs associated with the rule. The FAA anticipates that these modifications will reduce burdens associated with the requirements of the final rule on small entities without adversely affecting aviation safety.

#### International Trade Impact Statement

The final rule will affect only domestic operators and, therefore, will have no impact on trade opportunities for U.S. firms doing business overseas or on foreign firms doing business in the

United States. It should be noted that, unless compliance with this final rule would violate the domestic laws of policies of a foreign country or a foreign government contends that application of the rule raises questions of compatibility with foreign laws or policies, individuals employed at foreign repair stations under contract to U.S. certificate holders would not be able to perform maintenance or preventive maintenance work on U.S.-registered aircraft unless they participate in an anti-drug program. Thus, foreign repair stations may be affected economically. Likewise, this program also will result in an expense to U.S. certificate holders operating overseas because these entities will be required to establish anti-drug programs, which will not be required of their foreign competitors. The FAA is unable to estimate the possible competitive effect of these costs.

#### Paperwork Reduction Act Approval

In order to ensure compliance and effectiveness of the final rule, the FAA included necessary reporting and recordkeeping requirements in the provisions of the final rule. The final rule requires employers to maintain records related to employee drug testing and any rehabilitation and to submit periodic, written reports to the FAA that summarize an employer's anti-drug program. In accordance with the Paperwork Reduction Act of 1980, the recordkeeping and reporting requirements of the final rule have been submitted to the Office of Management and Budget (OMB) for approval.

#### Federalism Implications

The final rule adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. This rule preempts any State or local law that would prohibit or limit drug testing required under the rule. This preemption, under the FAA's statutory authority, is essential to ensure that the safety benefits are obtained throughout the nation's air transportation system. The rule also could have an indirect, economic impact on State and local governments, if persons who lose jobs as a result of a positive drug test require welfare benefits or other public social services. The FAA does not expect this impact to be significant, however. Therefore, in accordance with Executive Order 12612, the FAA determines that this final rule does not have sufficient federalism implications to warrant preparation of a Federalism Assessment.

#### Conclusion

The final rule requires domestic and supplemental air carriers, commercial operators of large aircraft, air taxi and commuter operators, certain commercial operators, certain contractors to these operators, located in the United States or in a foreign country, and air traffic control facilities not operated by the FAA or the U.S. military to have an anti-drug program for employees who perform, either in the United States or in a foreign country, sensitive safety- or security-related functions. Testing under this final rule will be conducted by an employer prior to employment, periodically, randomly, after an accident, based on reasonable cause, and after an employee returns to duty to perform a sensitive safety- or security-related function for an employer. The final rule also will require that an employer provide EAP education and training services to employees and supervisors. The rule is necessary to prohibit an employee from performing a sensitive safety- or security-related function for an employer while that employee has a prohibited drug in his or her system or if that employee has used drugs as evidenced by a drug test showing the presence of drugs or drug metabolites. The rule is intended to ensure a drug-free aviation workforce and to eliminate drug use and abuse in commercial aviation. The FAA believes that the final rule will reduce the potential for drug-related aviation accidents and will foster identification of commercial aviation employees who use drugs.

Pursuant to the terms of the Regulatory Flexibility Act of 1980, the FAA certifies that the final rule may have a significant negative economic impact on a substantial number of small entities. The final rule will not result in an annual effect on the economy of \$100 million or more, but because the requirements of the final rule are important and costly undertakings, the FAA considers the final rule to be a major rule pursuant to the criteria of Executive Order 12291. In addition, the rule involves issues of substantial interest to the public; thus, the FAA determines that the final rule is significant under the Regulatory Policies and Procedures of the Department of Transportation (44 FR 11034; February 2, 1979).

#### List of Subjects

##### 14 CFR Part 61

Air safety, Air transportation, Aircraft, Aircraft pilots, Airmen,

Aviation safety, Drug abuse, Drugs, Narcotics, Pilots, Safety, Transportation.

#### 14 CFR Part 63

Air safety, Air transportation, Aircraft, Airmen, Airplanes, Aviation safety, Drug abuse, Drugs, Narcotics, Safety, Transportation.

#### 14 CFR Part 65

Air safety, Air transportation, Aircraft, Airmen, Aviation safety, Drug abuse, Drugs, Narcotics, Safety, Transportation.

#### 14 CFR Part 121

Air carriers, Air transportation, Aircraft, Aircraft pilots, Airmen, Airplanes, Aviation safety, Drug abuse, Drugs, Narcotics, Pilots, Safety, Transportation.

#### 14 CFR Part 135

Air carriers, Air taxi, Air transportation, Aircraft, Airmen, Airplanes, Aviation safety, Drug abuse, Drugs, Narcotics, Pilots, Safety, Transportation.

#### The Amendment

Accordingly, the FAA amends Parts 61, 63, 65, 121, and 135 of the Federal Aviation Regulations (14 CFR Parts 61, 63, 65, 121, and 135) as follows:

#### PART 61—CERTIFICATION: PILOTS AND FLIGHT INSTRUCTORS

1. The authority citation for Part 61 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1355, 1421, 1422, and 1427; 49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983).

2. By adding a new § 61.14 to read as follows:

##### § 61.14 Refusal to submit to a drug test.

(a) This section applies to—

(1) An employee who performs a function listed in Appendix I to Part 121 of this chapter for a Part 121 certificate holder or a Part 135 certificate holder; and

(2) An employee who performs a function listed in Appendix I to Part 121 of this chapter for an operator as defined in § 135.1(c) of this chapter. An employee of a person conducting operations of foreign civil aircraft navigated within the United States pursuant to Part 375 or emergency mail service operations pursuant to Section 405(h) of the Federal Aviation Act of 1958 is excluded from the requirements of this section.

(b) Refusal by the holder of a certificate issued under this part to take a test for a drug specified in Appendix I to Part 121 of this chapter when requested by a certificate holder, by an

operator as defined in § 135.1(c) of this chapter, by a local law enforcement officer under his or her own authority, or by an FAA inspector, under the circumstances specified in that appendix, is grounds for—

(1) Denial of an application for any certificate or rating issued under this part for a period of up to 1 year after the date of that refusal; and

(2) Suspension or revocation of any certificate or rating issued under this part.

#### PART 63—CERTIFICATION: FLIGHT CREWMEMBERS OTHER THAN PILOTS

3. The authority citation for Part 63, Subpart A, is revised to read as follows:

Authority: 49 U.S.C. 1354(a), 1355, 1421, 1422, 1427, 1429, and 1430; 49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983).

4. By adding a new § 63.12b to read as follows:

##### § 63.12b Refusal to submit to a drug test.

(a) This section applies to—

(1) An employee who performs a function listed in Appendix I to Part 121 of this chapter for a Part 121 certificate holder or a Part 135 certificate holder; and

(2) An employee who performs a function listed in Appendix I to Part 121 of this chapter for an operator as defined in § 135.1(c) of this chapter. An employee of a person conducting operations of foreign civil aircraft navigated within the United States pursuant to Part 375 or emergency mail service operations pursuant to section 405(h) of the Federal Aviation Act of 1958 is excluded from the requirements of this section.

(b) Refusal by the holder of a certificate issued under this part to take a test for a drug specified in Appendix I to Part 121 of this chapter when requested by a certificate holder, by an operator as defined in § 135.1(c) of this chapter, by a local law enforcement officer under his or her own authority, or by an FAA inspector, under the circumstances specified in that appendix, is grounds for—

(1) Denial of an application for any certificate or rating issued under this part for a period of up to 1 year after the date of that refusal; and

(2) Suspension or revocation of any certificate or rating issued under this part.

#### PART 65—CERTIFICATION: AIRMEN OTHER THAN FLIGHT CREWMEMBERS

5. The authority citation for Part 65 continues to read as follows:

Authority: 49 U.S.C. 1354, 1355, 1421, 1422, and 1427; 49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983).

6. By adding a new § 65.23 to read as follows:

##### § 65.23 Refusal to submit to a drug test.

(a) This section applies to—

(1) An employee who performs a function listed in Appendix I to Part 121 of this chapter for a Part 121 certificate holder or a Part 135 certificate holder;

(2) An employee who performs a function listed in Appendix I to Part 121 of this chapter for an operator as defined in § 135.1(c) of this chapter. An employee of a person conducting operations of foreign civil aircraft navigated within the United States pursuant to Part 375 or emergency mail service operations pursuant to section 405(h) of the Federal Aviation Act of 1958 is excluded from the requirements of this section; and

(3) An employee of an air traffic control facility not operated by, or under contract with, the FAA or the U.S. military.

(b) Refusal by the holder of a certificate issued under this part to take a test for a drug specified in Appendix I to Part 121 of this chapter when requested by a certificate holder, by an operator as defined in § 135.1(c) of this chapter, by an employer as defined in § 65.46 of this part, by a local law enforcement officer under his or her own authority, or by an FAA inspector, under the circumstances specified in that appendix, is grounds for—

(1) Denial of an application for any certificate or rating issued under this part for a period of up to 1 year after the date that that refusal; and

(2) Suspension or revocation of any certificate or rating issued under this part.

7. By adding a new § 65.46 to read as follows:

##### § 65.46 Use of prohibited drugs.

(a) The following definitions apply for the purposes of this section:

(1) An "employee" is a person who performs an air traffic control function for an employer. For the purpose of this section, a person who performs such a function pursuant to a contract with an employer is considered to be performing that function for the employer.

(2) An "employer" means an air traffic control facility not operated by, or under contract with, the FAA or the U.S. military that employs a person to perform an air traffic control function.

(b) Each employer shall provide each employee performing a function listed in Appendix I to Part 121 of this chapter

and his or her supervisor with the training specified in that appendix. No employer may use any contractor to perform an air traffic control function unless that contractor provides each of its employees performing that function for the employer and his or her supervisor with the training specified in that appendix.

(c) No employer may knowingly use any person to perform, nor may any person perform for an employer, either directly or by contract, any air traffic control function while that person has a prohibited drug, as defined in Appendix I to Part 121 of this chapter, in his or her system.

(d) Except as provided in paragraph (e) of this section, no employer may knowingly use any person to perform, nor may any person perform for an employer, either directly or by contract, any air traffic control function if that person failed a test or refused to submit to a test required by Appendix I to Part 121 of this chapter given by a certificate holder, by an employer, or by an operator as defined in § 135.1(c) of this chapter.

(e) Paragraph (d) of this section does not apply to a person who has received a recommendation to be hired or to return to duty from a medical review officer in accordance with Appendix I to Part 121 of this chapter or who has received a special issuance medical certificate after evaluation by the Federal Air Surgeon for drug dependency in accordance with Part 67 of this chapter.

(f) Each employer shall test each of its employees who performs any air traffic control function in accordance with Appendix I to Part 121 of this chapter. No employer may use any contractor to perform any air traffic control function unless that contractor tests each employee performing such a function for the employer in accordance with that appendix.

#### **PART 121—CERTIFICATION AND OPERATIONS: DOMESTIC, FLAG, AND SUPPLEMENTAL AIR CARRIERS AND COMMERCIAL OPERATORS OF LARGE AIRCRAFT**

8. The authority citation for Part 121 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1355, 1356, 1357, 1401, 1421–1430, 1472, 1485, and 1502; 49 U.S.C. 106(g) (Revised, Pub. L. 97–449, January 12, 1983).

9. By adding a new § 121.429 to read as follows:

##### **§ 121.429 Prohibited drugs.**

(a) Each certificate holder shall provide each employee performing a

function listed in Appendix I to this part and his or her supervisor with the training specified in that appendix.

(b) No certificate holder may use any contractor to perform a function listed in Appendix I to this part unless that contractor provides each of its employees performing that function for the certificate holder and his or her supervisor with the training specified in that appendix.

10. By adding a new § 121.455 to read as follows:

##### **§ 121.455 Use of prohibited drugs.**

(a) This section applies to persons who perform a function listed in Appendix I to this part for the certificate holder. For the purpose of this section, a person who performs such a function pursuant to a contract with the certificate holder is considered to be performing that function for the certificate holder.

(b) No certificate holder may knowingly use any person to perform, nor may any person perform for a certificate holder, either directly or by contract, any function listed in Appendix I to this part while that person has a prohibited drug, as defined in that appendix, in his or her system.

(c) Except as provided in paragraph (d) of this section, no certificate holder may knowingly use any person to perform, nor may any person perform for a certificate holder, either directly or by contract, any function listed in Appendix I to this part if that person failed a test or refused to submit to a test required by that appendix given by a certificate holder or an operator as defined in § 135.1(c) of this chapter.

(d) Paragraph (c) of this section does not apply to a person who has received a recommendation to be hired or to return to duty from a medical review officer in accordance with Appendix I to Part 121 of this chapter or who has received a special issuance medical certificate after evaluation by the Federal Air Surgeon for drug dependency in accordance with Part 67 of this chapter.

11. By adding a new § 121.457 to read as follows:

##### **§ 121.457 Testing for prohibited drugs.**

(a) Each certificate holder shall test each of its employees who performs a function listed in Appendix I to this part in accordance with that appendix.

(b) No certificate holder may use any contractor to perform a function listed in Appendix I to this part unless that contractor tests each employee performing such a function for the certificate holder in accordance with that appendix.

12. By adding a new Appendix I to Part 121 to read as follows:

#### **Appendix I—Drug Testing Program**

This appendix contains the standards and components that must be included in an anti-drug program required by this chapter.

I. *DOT Procedures.* Each employer shall ensure that drug testing programs conducted pursuant to this regulation comply with the requirements of this appendix and the "Procedures for Transportation Workplace Drug Testing Programs" published by the Department of Transportation (DOT) (49 CFR Part 40). An employer may not use or contract with any drug testing laboratory that is not certified by the Department of Health and Human Services (DHHS) pursuant to the DHHS "Mandatory Guidelines for Federal Workplace Drug Testing Programs" (53 FR 11970; April 11, 1988).

II. *Definitions.* For the purpose of this appendix, the following definitions apply:

"Accident" means an occurrence associated with the operation of an aircraft which takes place between the time any person boards the aircraft with the intention of flight and all such persons have disembarked, and in which any person suffers death or serious injury, or in which the aircraft receives substantial damage (49 CFR 830.2).

"Annualized rate" for the purposes of unannounced testing of employees based on random selection means the percentage of specimen collection and testing of employees performing a function listed in section III of this appendix during a calendar year. The employer shall determine the annualized percentage rate by referring to the total number of employees performing a sensitive safety- or security-related function for the employer at the beginning of a calendar year or by an alternative method specified in the employer's drug testing plan approved by the FAA.

"Employee" is a person who performs, either directly or by contract, a function listed in section III of this appendix for a Part 121 certificate holder, a Part 135 certificate holder, an operator as defined in § 135.1(c) of this chapter (except operations of foreign civil aircraft navigated within the United States pursuant to Part 375 or emergency mail service operations pursuant to section 405(h) of the Federal Aviation Act of 1958), or an air traffic control facility not operated by, or under contract with, the FAA or the U.S. military. Provided however that an employee who works for an employer who holds a Part 135 certificate and who also holds a Part 121 certificate is considered to be an employee of the Part 121 certificate holder for the purposes of this appendix.

"Employer" is a Part 121 certificate holder, a Part 135 certificate holder, an operator as defined in § 135.1(c) of this chapter (except operations of foreign civil aircraft navigated within the United States pursuant to Part 375 or emergency mail service operations pursuant to Section 405(h) of the Federal Aviation Act of 1958), or an air traffic control facility not operated by, or under contract with, the FAA or the U.S. military. Provided, however, that an employer may use a person

to perform a function listed in section III of this appendix, who is not included under that employer's drug program, if that person is subject to the requirements of another employer's FAA-approved anti-drug program.

"Failing a drug test" means that the test result shows positive evidence of the presence of a prohibited drug or drug metabolite in an employee's system.

"Passing a drug test" means that the test result does not show positive evidence of the presence of a prohibited drug or drug metabolite in an employee's system.

"Positive evidence" means the presence of a drug or drug metabolite in a urine sample at or above the test levels listed in the DOT "Procedures for Transportation Workplace Drug Testing Programs" (49 CFR Part 40).

"Prohibited drug" means marijuana, cocaine, opiates, phencyclidine (PCP), amphetamines, or a substance specified in Schedule I or Schedule II of the Controlled Substances Act, 21 U.S.C. 811, 812 (1981 & 1987 Cum.P.P.), unless the drug is being used as authorized by a legal prescription or other exemption under Federal, state, or local law.

"Refusal to submit" means refusal by an individual to provide a urine sample after he or she has received notice of the requirement to be tested in accordance with this appendix.

III. *Employees Who Must Be Tested.* Each person who performs a function listed in this section must be tested pursuant to an FAA-approved anti-drug program conducted in accordance with this appendix:

- a. Flight crewmember duties.
- b. Flight attendant duties.
- c. Flight instruction or ground instruction duties.
- d. Flight testing duties.
- e. Aircraft dispatcher or ground dispatcher duties.
- f. Aircraft maintenance or preventive maintenance duties.
- g. Aviation security or screening duties.
- h. Air traffic control duties.

IV. *Substances For Which Testing Must Be Conducted.* Each employer shall test each employee who performs a function listed in section III of this appendix for evidence of marijuana, cocaine, opiates, phencyclidine (PCP), and amphetamines during each test required by section V of this appendix. As part of reasonable cause drug testing program established pursuant to this part, employers may test for drugs in addition to those specified in this part only with approval granted by the FAA under 49 CFR Part 40 and for substances for which the Department of Health and Human Services has established an approved testing protocol and positive threshold.

V. *Types of Drug Testing Required.* Each employer shall conduct the following types of testing in accordance with the procedures set forth in this appendix and the DOT "Procedures for Transportation Workplace Drug Testing Programs" (49 CFR Part 40):

A. *Preemployment testing.* No employer may hire any person to perform a function listed in section III of this appendix unless the applicant passes a drug test for that employer. The employer shall advise an applicant at the time of application that preemployment testing will be conducted to

determine the presence of marijuana, cocaine, opiates, phencyclidine (PCP), and amphetamines or a metabolite of those drugs in the applicant's system.

B. *Periodic testing.* Each employee who performs a function listed in section III of this appendix for an employer and who is required to undergo a medical examination under Part 67 of this chapter, shall submit to a periodic drug test. The employee shall be tested for the presence of marijuana, cocaine, opiates, phencyclidine (PCP), and amphetamines or a metabolite of those drugs as part of the first medical evaluation of the employee during the first calendar year of implementation of the employer's anti-drug program. An employer may discontinue periodic testing of its employees after the first calendar year of implementation of the employer's anti-drug program when the employer has implemented an unannounced testing program based on random selection of employees.

C. *Random testing.* Each employer shall randomly select employees who perform a function listed in section III of this appendix for the employer for unannounced drug testing. The employer shall randomly select employees for unannounced testing for the presence of marijuana, cocaine, opiates, phencyclidine (PCP), and amphetamines or a metabolite of those drugs in an employee's system using a random number table or a computer-based, number generator that is matched with an employee's social security number, payroll identification number, or any other alternative method approved by the FAA.

(1) During the first 12 months following implementation of unannounced testing based on random selection pursuant to this appendix, an employer shall meet the following conditions:

(a) The unannounced testing based on random selection of employees shall be spread reasonably throughout the 12-month period.

(b) The last collection of specimens for random testing during the year shall be conducted at an annualized rate equal to not less than 50 percent of employees performing a function listed in section III of this appendix.

(c) The total number of unannounced tests based on random selection during the 12-months shall be equal to not less than 25 percent of the employees performing a function listed in section III of this appendix.

(2) Following the first 12 months, an employer shall achieve and maintain an annualized rate equal to not less than 50 percent of employees performing a function listed in section III of this appendix.

D. *Postaccident testing.* Each employer shall test each employee who performs a function listed in section III of this appendix for the presence of marijuana, cocaine, opiates, phencyclidine (PCP), and amphetamines or a metabolite of those drugs in the employee's system if that employee's performance either contributed to an accident or cannot be completely discounted as a contributing factor to the accident. The employer shall be tested as soon as possible but not later than 32 hours after the accident. The decision not to administer a test under

this section must be based on a determination, using the best information available at the time of the accident, that the employee's performance could not have contributed to the accident. The employee shall submit to postaccident testing under this section.

E. *Testing based on reasonable cause.* Each employer shall test each employee who performs a function listed in section III of this appendix and who is reasonably suspected of using a prohibited drug. Each employer shall test an employee's specimen for the presence of marijuana, cocaine, opiates, phencyclidine (PCP), and amphetamines or a metabolite of those drugs. An employer may test an employee's specimen for the presence of other prohibited drugs or drug metabolites only in accordance with this appendix and the DOT "Procedures for Transportation Workplace Drug Testing Programs" (49 CFR Part 40). At least two of the employee's supervisors, one of whom is trained in detection of the possible symptoms of drug use, shall substantiate and concur in the decision to test an employee who is reasonably suspected of drug use. In the case of an employer holding a Part 135 certificate who employs 50 or fewer employees who perform a function listed in section III of this appendix or an operator as defined in § 135.1(c) of this chapter, one supervisor, who is trained in detection of possible symptoms of drug use, shall substantiate the decision to test an employee who is reasonably suspected of drug use. The decision to test must be based on a reasonable and articulable belief that the employee is using a prohibited drug on the basis of specific, contemporaneous physical, behavioral, or performance indicators of probable drug use.

F. *Testing after return to duty.* Each employer shall implement a reasonable program of unannounced testing of each individual who has been hired and each employee who has returned to duty to perform a function listed in section III of this appendix after failing a drug test conducted in accordance with this appendix or after refusing to submit to a drug test required by this appendix. The individual or employee shall be subject to unannounced testing for not more than 60 months after the individual has been hired or the employee has returned to duty to perform a function listed in section III of this appendix.

VI. *Administrative Matters.—A. Collection, testing, and rehabilitation records.* Each employer shall maintain all records related to the collection process, including all logbooks and certification statements, for two years. Each employer shall maintain records of employee confirmed positive drug test results and employee rehabilitation for five years. The employer shall maintain records of negative test results for 12 months. The employer shall permit the Administrator or the Administrator's representative to examine these records.

B. *Laboratory inspections.* The employer shall contract only with a laboratory that permits pre-award inspections by the employer before the laboratory is awarded a testing contract and unannounced inspections, including examination of any

and all records at any time by the employer, the Administrator, or the Administrator's representative.

**C. Employee request to retest a specimen.** Not later than 60 days after receipt of a confirmed positive test result, an employee may submit a written request to the MRO for retesting of the specimen producing the positive test result. Each employee may make one written request that a sample of the specimen be provided to the original or another DHHS-certified laboratory for testing. The laboratories shall follow chain-of-custody procedures. The employee shall pay the costs of the additional test and all handling and shipping costs associated with the transfer of the specimen to the laboratory.

**D. Release of Drug Testing Information.** An employer may release information regarding an employee's drug testing results or rehabilitation to a third party only with the specific, written consent of the employee authorizing release of the information to an identified person. Information regarding an employee's drug testing results or rehabilitation may be released to the National Transportation Safety Board as part of an accident investigation, to the FAA upon request, or as required by section VII.C.5 of this appendix.

**VII. Review of Drug Testing Results.** The employer shall designate or appoint a medical review officer (MRO). If the employer does not have a qualified individual on staff to serve as MRO, the employer may contract for the provision of MRO services as part of its drug testing program.

**A. MRO qualifications.** The MRO must be a licensed physician with knowledge of drug abuse disorders.

**B. MRO duties.** The MRO shall perform the following functions for the employer:

1. Review the results of the employer's drug testing program before the results are reported to the employer and summarized for the FAA.

2. Within a reasonable time, notify an employee of a confirmed positive test result.

3. Review and interpret each confirmed positive test result in order to determine if there is an alternative medical explanation for the confirmed positive test result. The MRO shall perform the following functions as part of the review of a confirmed positive test result:

a. Provide an opportunity for the employee to discuss a positive test result with the MRO.

b. Review the employee's medical history and any relevant biomedical factors.

c. Review all medical records made available by the employee to determine if a confirmed positive test result from legally prescribed medication.

d. Verify that the laboratory report and assessment are correct. The MRO shall be authorized to request that the original specimen be reanalyzed to determine the accuracy of the reported test result.

4. Process employee requests to retest a specimen in accordance with section VI.C of this appendix.

5. Determine whether and when, consistent with an employer's anti-drug program, a return-to-duty recommendation for a current employee or a decision to hire an individual

to perform a function listed in section III of this appendix after failing a test conducted in accordance with this appendix or after refusing to submit to a test required by this appendix, including review of any rehabilitation program in which the individual or employee participated, may be made.

6. Ensure that an individual or employee has been tested in accordance with the procedures of this appendix and the DOT "Procedures for Transportation Workplace Drug Testing Programs" (49 CFR Part 40) before the individual is hired or the employee returns to duty.

7. Determine a schedule of unannounced testing for an individual who has been hired or an employee who has returned to duty to perform a function listed in section III of this appendix after the individual or employee has failed a drug test conducted in accordance with this appendix or has refused to submit to a drug test required by this appendix.

**C. MRO determinations.** 1. If the MRO determines, after appropriate review, that there is a legitimate medical explanation for the confirmed positive test result that is consistent with legal drug use, the MRO shall conclude that the test result is negative and shall report the test as a negative test result.

2. If the MRO determines, after appropriate review, that there is no legitimate medical explanation for the confirmed positive test result that is consistent with legal drug use, the MRO shall refer the employee to an employer's rehabilitation program is available or to a personnel or administrative officer for further proceedings in accordance with the employer's anti-drug program.

3. Based on a review of laboratory inspection reports, quality assurance and quality control data, and other drug test results, the MRO may conclude that a particular drug test result is scientifically insufficient for further action. Under these circumstances, the MRO shall conclude that the test is negative for the presence of drugs or drug metabolites in an employee's system.

4. In order to make a recommendation to hire an individual to perform a function listed in section III of this appendix or to return an employee to duty to perform a function listed in section III of this appendix after the individual or employee has failed a drug test conducted in accordance with this appendix or refused to submit to a drug test required by this appendix, the MRO shall—

a. Ensure that the individual or employee is drug free based on a drug test that shows no positive evidence of the presence of a drug or a drug metabolite in the person's system;

b. Ensure that the individual or employee has been evaluated by a rehabilitation program counselor for drug use or abuse; and

c. Ensure that the individual or employee demonstrates compliance with any conditions or requirements of a rehabilitation program in which the person participated.

5. Notwithstanding any other section in this appendix, the MRO shall make the following determinations in the case of an employee or applicant who holds, or is required to hold, a medical certificate issued pursuant to Part 67 of this chapter in order to perform a function listed in section III of this appendix for an employer:

a. The MRO shall make a determination of probable drug dependence or nondependence as specified in Part 67 of this chapter. If the MRO makes a determination of nondependence, the MRO has authority to recommend that the employee return to duty in a position that requires the employee to hold a certificate issued under Part 67 of this chapter. The MRO shall forward the determination of nondependence, the return-to-duty decision, and any supporting documentation to the Federal Air Surgeon for review.

b. If the MRO makes a determination of probable drug dependence at any time, the MRO shall report the name of the individual and identifying information, the determination of probable drug dependence, and any supporting documentation to the Federal Air Surgeon. The MRO does not have the authority to recommend that the employee return to duty in a position that requires the employee to hold a certificate issued under Part 67 of this chapter. The Federal Air Surgeon shall determine if the individual may retain or may be issued a medical certificate consistent with the requirements of Part 67 of this chapter.

c. The MRO shall report to the Federal Air Surgeon the name of any employee who is required to hold a medical certificate issued pursuant to Part 67 of this chapter and who fails a drug test. The MRO shall report to the Federal Air Surgeon the name of any person who applies for a position that requires the person to hold a medical certificate issued pursuant to Part 67 of this chapter and who fails a preemployment drug test.

d. The MRO shall forward the information specified in paragraphs (a), (b), and (c) of this section to the Federal Air Surgeon, Federal Aviation Administration, Drug Abatement Branch (AAM-220), 800 Independence Avenue, SW., Washington, DC 20591.

**VIII. Employee Assistance Program (EAP).** The employer shall provide an EAP for employees. The employer may establish the EAP as a part of its internal personnel services or the employer may contract with an entity that will provide EAP services to an employee. Each EAP must include education and training on drug use for employees and training for supervisors making determinations for testing of employees based on reasonable cause.

**A. EAP education program.** Each EAP education program must include at least the following elements: display and distribution of informational material; display and distribution of a community service hot-line telephone number for employee assistance; and display and distribution of the employer's policy regarding drug use in the workplace.

**B. EAP training program.** Each employer shall implement a reasonable program of initial training for employees. The employee training program must include at least the following elements: The effects and consequences of drug use on personal health, safety, and work environment; the manifestations and behavioral cues that may indicate drug use and abuse; and documentation of training given to employees and employer's supervisory personnel. The

employer's supervisory personnel who will determine when an employee is subject to testing based on reasonable cause shall receive specific training on the specific, contemporaneous physical, behavioral, and performance indicators of probable drug use in addition to the training specified above. The employer shall ensure that supervisors who will make reasonable cause determinations receive at least 60 minutes of initial training. The employer shall implement a reasonable recurrent training program for supervisory personnel making reasonable cause determinations during subsequent years. The employer shall identify the employee and supervisor EAP training in the employer's drug testing plan submitted to the FAA for approval.

**IX. Employer's Drug Testing Plan.—A. Schedule for submission of plans and implementation.** (1) Each employer shall submit a drug testing plan to the Federal Aviation Administration, Office of Aviation Medicine, Drug Abatement Branch (AAM-220), 800 Independence Avenue, SW., Washington, DC 20591.

(2) Each employer who holds a Part 121 certificate and each employer who holds a Part 135 certificate and employs more than 50 employees who perform a function listed in section III of this appendix shall submit an anti-drug program to the FAA (specifying the procedures for all testing required by this appendix) not later than 120 days after December 21, 1988. Each employer shall implement preemployment testing of applicants for a position to perform a function listed in section III of this appendix not later than 10 days after approval of the plan by the FAA. Each employer shall implement the remainder of the employer's anti-drug program no later than 180 days after approval of the plan by the FAA.

(3) Each employer who holds a Part 135 certificate and employs from 11 to 50 employees who perform a function listed in section III of this appendix shall submit an interim anti-drug program to the FAA (specifying the procedures for preemployment testing, periodic testing, postaccident testing, testing based on reasonable cause, and testing after return to duty) not later than 180 days after December 21, 1988. Each employer shall implement the interim anti-drug program not later than 180 days after approval of the plan by the FAA. Each employer shall submit an amendment to its approved anti-drug program to the FAA (specifying the procedures for unannounced testing based on random selection) not later than 120 days after approval of the interim anti-drug program by the FAA. Each employer shall implement the random testing provision of its amended anti-drug program not later than 180 days after approval of the amendment.

(4) Each employer who holds a Part 135 certificate and employs 10 or fewer employees who perform a function listed in section III of this appendix, each operator as defined in § 135.1(c) of this chapter, and each air traffic control facility not operated by, or under contract with the FAA or the U.S. military, shall submit an anti-drug program to the FAA (specifying the procedures for all testing required by this appendix) not later

than 360 days after December 21, 1988. Each employer shall implement the employer's anti-drug program not later than 180 days after approval of the plan by the FAA.

(5) Each employer or operator, who becomes subject to the rule as a result of the FAA's issuance of a Part 121 or Part 135 certificate or as a result of beginning operations listed in § 135.1(b) for compensation or hire (except operations of foreign civil aircraft navigated within the United States pursuant to Part 375 or emergency mail service operations pursuant to section 405(h) of the Federal Aviation Act of 1958) shall submit an anti-drug plan to the FAA for approval, within the timeframes of paragraphs (2), (3), or (4) of this section, according to the type and size of the category of operations. For purposes of applicability of the timeframes, the date that an employer becomes subject to the requirements of this appendix is substituted for [the effective date of the rule].

B. An employer's anti-drug plan must specify the methods by which the employer will comply with the testing requirements of this appendix. The plan must provide the name and address of the laboratory which has been selected by the employer for analysis of the specimens collected during the employer's anti-drug testing program.

C. An employer's anti-drug plan must specify the procedures and personnel the employer will use to ensure that a determination is made as to the veracity of test results and possible legitimate explanations for an employee failing a test.

D. The employer shall consider its anti-drug program to be approved by the Administrator, unless notified to the contrary by the FAA, within 60 days after submission of the plan to the FAA.

**X. Reporting Results of Drug Testing Program.** A. Each employer shall submit a semiannual report to the FAA summarizing the results of its drug testing program and covering the period from January 1–June 30. Each employer shall submit an annual report to the FAA summarizing the results of its drug testing program and covering the period from January 1–December 31. Each employer shall submit these reports no later than 45 days after the last day of the report period.

B. Each report shall contain:

1. The total number of tests performed and the total number of tests performed for each category of test.

2. The total number of positive test results by category of test; the total number of positive test results by each function listed in section III of this appendix; and the total number of positive test results by the type of drug shown in a positive test result.

3. The disposition of an individual who failed a drug test conducted in accordance with this appendix or who refused to submit to a drug test required by this appendix by each category of test.

**XI. Preemption.** A. The issuance of these regulations by the FAA preempts any State or local law, rule, regulation, order, or standard covering the subject matter of this rule, including but not limited to, drug testing of aviation personnel performing sensitive safety- or security-related functions.

B. The issuance of these regulations does not preempt provisions of State criminal law

that impose sanctions for reckless conduct of an individual that leads to actual loss of life, injury, or damage to property whether such provisions apply specifically to aviation employees or generally to the public.

**XII. Conflict with foreign laws or international law.** A. This appendix shall not apply to any person for whom compliance with this appendix would violate the domestic laws or policies of another country.

B. This appendix is not effective until January 1, 1990, with respect to any person for whom a foreign government contends that application of this appendix raises questions of compatibility with that country's domestic laws or policies. On or before December 1, 1989, the Administrator shall issue any necessary amendment resolving the applicability of this appendix to such person on or after January 1, 1990.

## PART 135—AIR TAXI OPERATORS AND COMMERCIAL OPERATORS

13. The authority citation for Part 135 continues to read as follows:

**Authority:** 49 U.S.C. 1354(a), 1355, 1421–1431, and 1502; 49 U.S.C. 106(g) (Revised, Pub. L. 97–449, January 12, 1983).

14. By revising the introductory text of § 135.1(b) and adding new paragraph (c) and (d) to read as follows:

### § 135.1 Applicability.

(b) Except as provided in paragraph (c) of this section, this part does not apply to—

(c) For the purpose of §§ 135.249, 135.251, and 135.353, "operator" means any person or entity conducting an operation listed in paragraph (b) of this section for compensation or hire except operation of foreign civil aircraft navigated within the United States pursuant to Part 375 described in paragraph (b)(8) and emergency mail service operation pursuant to section 405(h) of the Federal Aviation Act of 1958 described in paragraph (b)(9). Each operator and each employee of an operator shall comply with the requirements of §§ 135.249, 135.251, and 135.353 of this part.

(d) Notwithstanding the provisions of paragraph (c) of this section, an operator who does not hold a Part 121 certificate or a Part 135 certificate is permitted to use a person, who is otherwise authorized to perform aircraft maintenance or preventive maintenance duties and who is not subject to the requirements of an FAA-approved anti-drug program, to perform—

(1) Aircraft maintenance or preventive maintenance on the operator's aircraft if the operator would be required to transport the aircraft more than 50 nautical miles further than the closest

available repair point from the operator's principal place of operations to obtain these services; or

(2) Emergency repairs on the operator's aircraft if the aircraft cannot be safely operated to a location where an employee subject to the requirements of this appendix can perform the emergency repairs.

15. By adding a new § 135.249 to read as follows:

**§ 135.249 Use of prohibited drugs.**

(a) This section applies to persons who perform a function listed in Appendix I to Part 121 of this chapter for a certificate holder or an operator. For the purpose of this section, a person who performs such a function pursuant to a contract with the certificate holder or the operator is considered to be performing that function for the certificate holder or the operator.

(b) No certificate holder or operator may knowingly use any person to perform, nor may any person perform for a certificate holder or an operator, either directly or by contract, any function listed in Appendix I to Part 121 of this chapter while that person has a prohibited drug, as defined in that appendix, in his or her system.

(c) Except as provided in paragraph (d) of this section, no certificate holder or operator may knowingly use any person to perform, nor may any person perform for a certificate holder or an operator, either directly or by contract, any function listed in Appendix I to Part 121 of this chapter if that person has failed a test or refused to submit to a test required by that appendix given by any certificate holder or any operator.

(d) Paragraph (c) of this section does not apply to a person who has received a recommendation to be hired or to return to duty from a medical review officer in accordance with Appendix I to Part 121 of this chapter or who has received a special issuance medical certificate after evaluation by the Federal Air Surgeon for drug dependency in accordance with Part 67 of this chapter.

16. By adding a new § 135.251 to read as follows:

**§ 135.251 Testing for prohibited drugs.**

(a) Each certificate holder or operator shall test each of its employees who performs a function listed in Appendix I to Part 121 of this chapter in accordance with that appendix.

(b) No certificate holder or operator may use any contractor to perform a

function listed in Appendix I to Part 121 of this chapter unless that contractor tests each employee performing such a function for the certificate holder or operator in accordance with that appendix.

17. By adding a new § 135.353 to read as follows:

**§ 135.353 Prohibited drugs.**

(a) Each certificate holder or operator shall provide each employee performing a function listed in Appendix I to Part 121 of this chapter and his or her supervisor with the training specified in that appendix.

(b) No certificate holder or operator may use any contractor to perform a function specified in Appendix I to Part 121 of this chapter unless that contractor provides each of its employees performing that function for the certificate holder or the operator and his or her supervisor with the training specified in that appendix.

Issued in Washington, DC, on November 14, 1988.

T. Allan McArtor,  
Administrator.

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